UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF NEW YORK

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BLUE CROSS AND BLUE SHIELD OF NEW :
JERSEY, INC., et al., :
Plaintiffs, :
: 98 CIV. 3287(JBW)
v. :
PHILIP MORRIS INCORPORATED, et al., :
Defendants. :

- -X

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Video deposition of ALEXANDER W. SPEARS, III, Ph.D.

(Taken by Plaintiffs)

Greensboro, North Carolina

March 23, 2000

Reported by: Andrea L. Nobrega
Court Reporter
Notary Public

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UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK

- -X

THE NATIONAL ASBESTOS WORKERS MEDICAL FUND, et al.,

Plaintiffs,

v.

PHILIP MORRIS INCORPORATED (Philip Morris U.S.A., et al.,

Defendants.

: Case No. 989 Civ. 1492(JBW)

- -X

Video deposition of ALEXANDER W. SPEARS, III, Ph.D.

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Videotaped deposition of ALEXANDER W. SPEARS, III, Ph.D., taken by the Plaintiffs, at 230 North Elam Street, Greensboro, North Carolina, on the 23rd day of March, 2000 at 9:35 a.m., before Andrea L. Nobrega, Notary Public and Court Reporter.

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P R O C E E D I N G S

THE VIDEOGRAPHER: Today is March 23, 2000. The time is 9:35 a.m. Would the court reporter please swear in the witness.

Whereupon, ALEXANDER W. SPEARS, III, Ph.D., having been first duly sworn, was examined and testified as follows:

THE VIDEOGRAPHER: Counsel will now introduce themselves for the record.

MR. HEFTER: Michael Hefter from Dewey Ballantine on behalf of the BlueCross And BlueShield plaintiffs.

MR. CARBERRY: Paul Carberry from Dewey Ballantine on behalf of the plaintiffs.

MR. BROWN: Brian M. Brown from The Law Office of Peter G. Angelos, representing the plaintiffs in The National Asbestos Workers case.

MR. ALLINDER: William Allinder from Shook, Hardy & Bacon, for Lorillard Tobacco Company.

MS. CLARK: Jamie Clark, Shook, Hardy & Bacon, for Lorillard Tobacco Company.

MR. REILLY: John Reilly, associate general counsel for Lorillard Tobacco Company.

EXAMINATION BY COUNSEL FOR PLAINTIFFS
BLUE CROSS AND BLUE SHIELD OF NEW JERSEY, INC., ET AL.

BY MR. HEFTER:

Q. Dr. Spears, we introduced ourselves off the record

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a few minutes ago. My name is Michael Hefter, from the law firm of Dewey Ballantine, and we represent the plaintiffs in the BlueCross And BlueShield of New Jersey case. The reason why I say the BlueCross And BlueShield of New Jersey case is because you may be familiar with a case that was pending a year or two back in Minnesota that was brought on behalf of BlueCross And BlueShield of Minnesota, is that correct?

A. Yes, correct.

Q. When I use -- I will try to during the course of the deposition to use BlueCross And BlueShield of New Jersey so you can keep it clear in your mind that we are talking about this particular case and not about the State of Minnesota or BlueCross And BlueShield of Minnesota case. I know you have been deposed before and you have testified at trial before, but just a few ground rules.

I will be asking you questions and Mr. Allinder may object from time to time. Unless he instructs you not to answer, you can go ahead and answer the question. I will try not to talk over you, if you can try not to talk over me. That would be greatly appreciated. If you need a break at any period of time, just let me know and we'll be amenable and reasonable to letting you taking a break.

A. All right.

Q. You are currently the chairman of the Lorillard Tobacco Company, is that correct?

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A. That's correct.

Q. When did you become the chairman of Lorillard Tobacco Company?

A. The beginning of this year. I was chairman and chief executive officer before that.

Q. When was the first time you became the chairman of the board of directors of Lorillard Tobacco Company?

A. I believe it was January 1, 1995.

Q. And I take it from your earlier answer that at some point you relinquished the post of chief executive officer of the company?

A. This past January.

Q. Would it be fair to say that as of January 1, 2000, is that the effective date of your --

A. Yes, that's correct.

Q. Who is the current chief executive officer of Lorillard Tobacco Company?

A. Martin Orlowski.

MR. HEFTER: What I would like to do now is mark Dr. Spears' expert report in this case as Spears Exhibit No. 1.

(Exhibit No. 1 marked for identification.)

BY MR. HEFTER:

Q. You can take a minute to look at the document.

A. Yes.

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Q. Have you seen this document before, Dr. Spears?
A. Yes, I have.
Q. When was the last time that you read this particular document?
A. I looked at it yesterday.
Q. And that would be -- would it be fair to say that was in preparation for your deposition today?
A. That's correct.
Q. Let me just go back for a second. Mr. Orlowski, was he an employee of the company prior to becoming chief executive officer of the company?
A. Yes, he was.
Q. How long has he been in the employ of Lorillard Tobacco Company?
A. About ten years.
Q. Do you have any current day-to-day management responsibilities at Lorillard?
A. Yes, I have some general responsibilities.
Q. Can you describe those for me?
A. Yes, I have been maintaining awareness of the scientific literature as it relates to smoking and health. I have continued my relationships in the community with respect to charitable giving. I am a member of various organizations and represent the company at those organizations, such as the chamber of commerce, chair of the United Way campaign,

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various community activities.

Q. Any other responsibilities that you can think of?

A. Well, I review reports, sales information, manufacturing information, inventory levels, and if I have concerns, I discuss them with Martin Orlowski.

Q. How often does the board of directors of Lorillard meet?

A. We meet quarterly.

Q. When was the last time that the board of directors of Lorillard met?

A. I don't have the exact date, but I believe it was February. I think it was February of this year.

Q. 2000?

A. Yes.

Q. In your capacity as the chairman of the board of Lorillard, do you report to Loews Corporation?

A. I have no formal reporting responsibility, but generally, yes.

Q. How do you report to Loews Corporation?

A. We generally bring the results of our meetings, declaration of dividends, that sort of thing.

Q. In your capacity as the chief executive officer at Lorillard, when you were the chief executive officer, did you have reporting obligations to Loews Corporation?

A. Yes, I had a reporting obligation as any

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shareholder, to a shareholder, Loews being our single shareholder.

Q. How would you report to Loews Corporation? Would that be in meetings, written reports?

A. They were verbal meetings, verbal discussions and meetings.

Q. And those verbal meetings, who did they take place with?

A. Andrew Tisch.

Q. What position does Mr. Tisch hold?

A. He is a member of the management committee of Loews.

Q. Does he have any management responsibility at Lorillard Tobacco Company?

A. No, he does not.

Q. When did Lorillard Tobacco Company become a wholly owned subsidiary of Loews, to the best of your recollection?

A. Well, Lorillard was acquired by Loews in 1969, I guess, and it was a division at that time of Loews Theatres, and I can't remember the exact date it became Lorillard, Inc., and now Lorillard Tobacco Company is a subsidiary of Lorillard, Inc., which in turn is a subsidiary of Loews.

Q. You indicated before that one of your responsibilities was maintaining awareness of scientific literature relating to smoking and health?

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A. Yes, that's correct.

Q. How do you maintain your awareness of the scientific literature relating to smoking and health?

A. Over the years I have read various abstracts, results of various abstracting services. Currently I receive reprints of articles in the literature that are selected in that they relate to smoking and health. We have an internal library that maintains an awareness of the literature, provides that kind of information, as well as our senior vice president of science and technology provides information to me.

Q. Who is the senior vice president of science and technology?

A. Chris Coggins.

Q. Is Mr. Coggins -- I presume it's Mr.?

A. Doctor.

Q. Does Dr. Coggins select the reprints of the articles that you review?

A. He provides me with copies of those that he is interested in as another source of information.

Q. Other than Mr. Coggins, is there another individual -- are there other individuals within Lorillard Tobacco Company that provide you with scientific articles?

A. Yes.

Q. Who are those individuals?

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A. Dan Heck is another individual, Dr. Heck.

Q. Any other individuals?

A. Other than the library, no.

Q. Do you have a direct contact person within the library with whom you communicate to get scientific literature?

A. Yes.

Q. Who is that person?

A. The head of the library which is Larry Skladenowski.

Q. Since January 1, 2000, how many articles in the scientific literature have you reviewed relating to smoking and health?

A. I don't know. I didn't count them. I probably reviewed a hundred or so.

Q. Do you recall the topics of any of those articles?

A. Well, I have generally reviewed articles on asbestos and smoking related to the subject of asbestos and smoking. I looked at a series that relates to generally fiber carcinogenesis beyond asbestos, mechanisms and so forth. I reviewed the IARC publication on fiber carcinogenesis. That's one that I recall. I reviewed an article which is a summary of the epidemiology on fibers in carcinogenesis, smoking, and the subject of synergy as it's described in the literature.

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I have reviewed articles recently on mesothelioma and on 40 virus. It's hard to remember everything that I looked at, but those are some subjects that came to mind.

Q. Would it be fair to say that the articles that you reviewed relating to asbestos and fiber carcinogenesis were in connection for preparation for your deposition in the Falise case?

A. Some were, but I reviewed many of these before that.

Q. In preparation for your deposition today, did you review any scientific literature?

A. No, not per se.

Q. Would it be fair to characterize your relinquishment of your post as CEO as retirement?

A. I retire at the end of this year.

Q. Why did you retire as the CEO of the company?

MR. ALLINDER: Objection.

THE WITNESS: Why did I retire, to reduce my responsibility and to be able to make the transition.

BY MR. HEFTER:

Q. Transition to?

A. From a CEO to retirement.

Q. As the CEO of Lorillard Tobacco Company, did you have a written employment contract?

A. I do for the last two years, yes.

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Q. Prior to the last two years you did not?

A. No, I didn't.

MR. ALLINDER: Let Mr. Hefter finish his questions before you answer.

BY MR. HEFTER:

Q. Prior to two years ago, you did not have a written employment contract?

A. That's correct.

Q. Did the company require you to enter into a written employment contract two years ago?

A. No. It was mutually agreed to.

Q. Why did the company require you to have a written employment contract?

MR. ALLINDER: Objection.

THE WITNESS: They did not. I proposed it.

BY MR. HEFTER:

Q. What were your reasons for having a written employment contract two years ago?

A. Basically to lay out the terms and conditions of the two years that I would work beyond age 65.

Q. Would it be fair to say that you are 67 right now?

A. That's right.

Q. Was one of the terms and conditions of your written employment contract to continue to testify in smoking and health litigation?

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A. No, it's not.

Q. Is that a provision in your written employment contract?

A. No, it's not.

Q. Were the terms of your compensation provided for in your written employment contract?

A. Yes.

Q. For the year -- would it be fair to say that your written employment contract spanned from 1998 to 1999 -- covered those two years, I should say?

A. Covers the years '99 to 2000.

Q. What was your salary for the year 1999?

A. Approximately $700,000.

Q. That is provided for in the written employment contract?

A. The contract calls it to continue my salary plus any -- would not preclude increases beyond that if it were so desired. That would be on behalf of the company, of course, to make those determinations, but it guaranteed that compensation level for a two year period.

Q. Would it be fair to say that your compensation for year 2000, your salary for the year 2000 is also $700,000?

A. That's correct.

Q. Other than your $700,000 salary, do you receive any compensation separate and apart from the $700,000 for acting

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as the chairman of the board?

A. I received a bonus each -- yes, I received a bonus.

Q. What was your bonus for the year 2000 -- pardon me, what was your bonus for the year 1999?

A. $170,000.

Q. Would it be fair to say that your bonus for the year 2000 hasn't been set yet?

A. That's correct.

Q. Do you receive compensation for attending board of directors meetings?

A. No, I do not.

Q. Did you receive any bonus at the time of your retirement apart from the bonus that you just specified?

A. I haven't retired. I'm an active employee.

Q. Thank you. Did you receive any bonus by virtue of your retirement as chief executive officer of Lorillard?

A. No, I did not.

Q. Do you own any stock in Loews Corporation?

A. No, I do not.

Q. Have you ever received stock in Loews Corporation as part of a compensation package that you have had at the company?

A. I received warrants and debentures, which I guess when Lorillard stock was -- Lorillard was an independent company prior to acquisition by Loews and I had some

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Lorillard stock which was turned into warrants and debentures of Loews, but that was back in 1969, maybe '70.

Q. The warrants and debentures that you received as a result of the acquisition of Lorillard by Loews, is that the only securities in Loews Corporation that you have received as part of the compensation at Lorillard?

MR. HEFTER: Objection.

THE WITNESS: That's correct.

BY MR. HEFTER:

Q. Would it be fair to say that you have sold the debentures you received as a result of the acquisition?

A. Yes, I have.

Q. Would it be fair to say that at some point you exercised the warrants on your stock in Loews Corporation?

A. I sold the warrants.

Q. In what year, if you can recall, did you sell the warrants?

A. Back in the '70s.

Q. Would it be also fair to say that you sold the debentures back in the '70s, too?

A. That's correct. I'm trying to remember. There may have been another stock option in the early '70s. It wasn't a significant number of dollars.

Q. Let me put it this way, within the past five years have you received any securities of Loews Corporation?

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A. No, I have not.

Q. Within the past five years, have you purchased any securities in Loews Corporation?

A. No, I have not.

Q. From 1995 to 1999 as the chairman and chief executive of Lorillard Tobacco Company, did you receive bonuses in those years?

A. No. 1999 -- 1998 was the first year of bonus.

Q. What was the bonus in that year that you received?

A. $150,000.

Q. Did I hear you correctly when you testified before that your current written employment contract covers the year 1999 and the year 2000?

A. That's correct.

Q. Do you have any understanding with the company to continue as chairman of the board of the company past the year 2000?

A. No, I do not.

Q. It is a possibility that you would continue as the chairman of the board after the year 2000, is that correct?

A. That's not my current intent.

Q. Your current intent is to retire as the chairman of the board of Lorillard Tobacco at the end of the year --

A. As an active employee, yes.

Q. Is there any deferred compensation plan at

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Lorillard today?

A. Not today.

Q. Upon your retirement, will you receive any deferred compensation as a result of your employment tenure at Lorillard Tobacco?

A. Yes, I will.

Q. Can you describe the deferred compensation that you will be receiving?

A. There was a plan that was in effect for -- I can't remember exactly -- maybe ten years, which you would defer up to a maximum of ten percent of your salary, and I deferred at that level for those periods. My monies earned interest at five and a half percent, as I recall. So that will be paid out upon retirement.

Q. Currently, have your rights vested with respect to the money that's in your deferred compensation account?

A. Yes, they are all vested.

Q. Do you know what the value of the --

A. I can't give you the exact value, but the order of 600 -- between $600,000 and $700,000.

Q. Do you own any securities in any other tobacco company?

A. No, I do not.

Q. Have you ever owned any securities in any other tobacco company?

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A. No, I have not.

Q. If you would turn, Dr. Spears, to your expert report. It indicates here that you have a bachelor of science from Allegheny College in 1953, is that correct?

A. That's correct.

Q. What was your bachelor's of science in? What degree did you earn?

A. Chemistry.

Q. You also have a Ph.D. in chemistry from the State University of New York in Buffalo, is that correct?

A. That's correct.

Q. And you received that degree in 1960?

A. That's correct.

Q. What was your they thesis, if you can recall?

A. Isolation identification of a naturally occurring tumor inhibitor.

Q. You earned your Ph.D. at the time that you were employed by Lorillard?

A. I finished the requirements. I went back and received the degree in February of 1960.

Q. In 1959, as a research associate, what were your responsibilities?

A. Well, I was in the laboratory and my first assignments were related to the determination of benzo(A)pyrene in tobacco smoke in a quantitative fashion. I

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also had the responsibility of reviewing the literature with respect to smoking and health.

Q. Did you determine at the time that benzo(A)pyrene was a particulate in tobacco smoke?

A. Well, it was -- it had been purported in the literature that benzo(A)pyrene was a component of tobacco smoke, although the methods for analysis at that time were subject to variation, I would say, in terms of a quantitative determination, and the purpose was to try to quantitatively determine the level of that material in tobacco smoke.

Q. Did you determine quantitatively the amount of benzo(A)pyrene in tobacco smoke?

A. Yes, after developing a method, yes.

Q. What were your conclusions?

A. Well, it was a program to try to reduce the amount of benzo(A)pyrene, and we looked at many things. We looked at the possibility of identifying a precursor in tobacco since this material is formed during the combustion and pyrolytic reactions that occur during the smoking process.

We looked at over time a lot of potential catalysts that you could add to tobacco to change the combustion properties to reduce the concentration of benzo(A)pyrene, as well as look at the precursor approach as I mentioned before. We looked at, over time again, many different materials, such as substitute tobacco materials, trying to understand how

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this material is formed and how you might inhibit.

Q. What is a precursor approach?

A. You are looking for the components in tobacco that give rise perhaps selectively to a compound in tobacco smoke. The precursor would be that component in tobacco if it exists.

Q. Did you determine at that point the amount of benzo(A)pyrene that's inhaled by a smoker?

MR. ALLINDER: Objection.

THE WITNESS: We were determining the amount in the cigarette smoke condensate that was collected from smoking of cigarettes in a mechanical smoking device.

BY MR. HEFTER:

Q. And did you determine the quantity based on that study?

A. That's correct, you collect the condensate and determine the quantity in the condensate.

Q. I guess what I'm looking for is a specific number that you determined based on that study?

A. I'm not talking about one study. I'm talking about many studies and the number varies depending on the particular study.

Q. You taught as an instructor of chemistry at Millard Fillmore College from 1958 to 1959?

A. That's correct.

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Q. Where is Millard Fillmore College located?
A. Buffalo, New York, part of the university.
Q. Would it be correct to state that your instruction was in entry level chemistry?
A. I think I taught maybe freshmen in organic chemistry, but this is the evening division -- at the time it was the evening division of the university.
Q. It would be fair to say that you weren't a tenured professor at Millard Fillmore College, is that correct?
A. That's correct.
Q. And you also were an assistant professor of chemistry at Guilford College from 1961 to '65?
A. That's correct.
Q. Would it be fair to say you were not a tenured professor at Guilford College?
A. No, I was not a tenure professor.
Q. Would it be fair to say that your instruction in chemistry at Guilford College was entry level chemistry?
A. No, that's not correct.
Q. What did you teach at Guilford College from 1961 to 1965 in the area of chemistry?
A. I taught all of the courses that a chemistry major would take. I taught first year in organic chemistry, analytical chemistry, organic chemistry, physical chemistry.
Q. During this time period did you teach any classes

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on toxicology?

A. No, I can not.

Q. Did you teach any classes on pharmacology?

A. No, this was chemistry, but part of pharmacology is chemistry.

Q. Would you say that -- strike that.

Would it be fair to say that your teaching in chemistry at Guilford College did not involve the subject of pharmacology as we know it today?

A. That's correct.

Q. Other than your Ph.D. in chemistry, do you have any other degrees?

A. No, I do not.

Q. Other than your teaching at Millard Fillmore College from 1958 and '59 and teaching at Guilford College from '61 to '65, have you taught at any other university in the United States?

A. No, I have not.

Q. Do you have any other teaching experience other than what's listed in Spears Exhibit No. 1?

A. I have given seminars.

Q. Where have you given seminars?

A. I gave one to the local American Chemical Society.

Q. Let me stop you there. When was that?

A. Back in the 1970s, maybe '60s.

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Q. Do you remember the topic of the seminar?
A. No, I don't.
Q. Other than the seminar to the local American Chemical Society, have you taught at any other seminars?
A. I have not taught. I have also given papers at scientific meetings.
Q. You wouldn't consider that teaching, however?
A. No, I would not.
Q. So other than your teaching experience at Millard Fillmore College from 1958 to 1959, and your assistant professorship at Guilford College, you don't have any other teaching experience other than the seminar at the local American Chemical Society?
MR. ALLINDER: Objection.
THE WITNESS: That's all that I recall.
BY MR. HEFTER:
Q. Would you consider yourself an expert in oncology?
A. I wouldn't consider myself an expert, but I consider myself knowledgeable.
Q. Knowledgeable about oncology?
A. Yes, depending on specifically what you mean. Oncology is a very large subject.
Q. Have you ever taught any classes on oncology?
A. No.
Q. Do you have a degree in oncology?

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A. No.

Q. Have you ever performed any cancer research?

MR. ALLINDER: Objection.

THE WITNESS: I would consider my thesis to be in the field of cancer research.

BY MR. HEFTER:

Q. Within the past ten years, have you conducted any cancer research?

MR. ALLINDER: Objection.

THE WITNESS: No.

BY MR. HEFTER:

Q. Within the past ten years, have you conducted any research in molecular biology?

A. I'm not sure I understand what you mean by have I conducted. Personally, the answer is no.

Q. That's my question.

A. The answer is no.

Q. Let's go back for a second to some questions I asked you before. Have you received any compensation -- separate and apart from your salary and bonus, have you received any compensation for testifying at any tobacco and health litigation?

A. No, I have not.

Q. What was your salary in 1995 when you became the CEO of Lorillard, if you can recall it?

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A. I can give you a ball park. I don't recall it, but I think in the range of 500,000.

Q. If you turn, Dr. Spears, to Exhibit No. 1 -- I'm referring to your CV -- which I believe is the sixth page of the exhibit. If you can look to the second page of your CV where it says related activities.

A. Yes.

Q. Can you just read that paragraph just to refresh your recollection of it. Have you had an opportunity to read it?

A. Yes, I have.

Q. Other than what's listed here, have you -- strike that.

Is that a full and complete list of the instances in which you have testified before regulatory or Congress in the United States?

MR. ALLINDER: Objection.

THE WITNESS: I believe it is.

BY MR. HEFTER:

Q. Have you ever testified before any state legislature or regulatory body concerning the issues of smoking and health?

A. I do not believe so.

Q. If you can turn to the list of publications, which is page six of your CV and just take a minute to scan down

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that list, please.

My question is, is this a complete listing of your publications?

A. I believe it is.

Q. Is the Journal of Fire Science a peer review publication?

A. Yes, it is.

Q. Is the CORESTA Information Bulletin a peer review publication?

A. What are you referring to?

Q. I'm sorry, I'm referring to on page eight of your CV, the last article that's noted there.

A. This was a presentation and this bulletin is a summary of the presentations that were given at that particular scientific meeting.

Q. But the CORESTA Information Bulletin is not a peer review?

A. No, it's not a peer review journal. This was an invited paper.

Q. Have you ever acted as a peer reviewer for any peer review journal?

A. Yes, I have.

Q. Which journals have you acted as a peer reviewer?

A. Analytical Chemistry, Tobacco Science. Those are the ones I recall.

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Q. Analytical Chemistry, when was the last time you acted as a peer reviewer?

A. Well, I don't remember the exact dated, but it would have been back in the time frame that I was publishing articles, so it would have been principally in the '60s and '70s.

Q. Do you recall how many articles you acted as a peer reviewer for during that time frame for Analytical Chemistry?

A. No, I do not.

Q. More than ten?

A. No, I don't think so.

Q. Do you recall the subject matter of any articles that you acted as a peer reviewer for in the publication of Analytical Chemistry?

A. No, I don't recall the particular titles of the articles.

Q. Do you recall if any of the articles that you acted as a peer reviewer for in Analytical Chemistry dealt with the issue of smoking?

A. I think most of those that I reviewed had something to do with the determination of components of tobacco smoke, or something related to the compounds that I had published on. It may have been independent tobacco smoke.

Q. The journal of Tobacco Science, when was the last time you acted as a peer reviewer for Tobacco Science?

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A. In the same time frame.

Q. So would it be fair to say that since the '60s or '70s you have not acted as a peer reviewer for a peer review journal?

A. That's correct.

Q. Just for my information, and for the information of everybody, I'm sure, what is spectroscopy?

MR. ALLINDER: Give me a reference, please.

MR. HEFTER: On page two of your CV. I'm sorry, page two of the report, and let me be more specific about that. If you go to page two of the report and you, the first full paragraph, starting I am currently a member, you say you are currently a member of the Society for Applied Spectroscopy.

THE WITNESS: Yes.

BY MR. HEFTER:

Q. What is applied spectroscopy?

A. It is the use of equipment for determination of -- can be determination of amounts of material, can be determination of structure of unknown compounds. It's a general technique where you divide the spectrum, electromagnetic spectrum which includes light, in visible regions, infrared regions, ultraviolet regions, where you divide the light into its respective wavelengths, and then determine which wavelengths are absorbed by the sample, and

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that is characteristic of individual compounds like a fingerprint, so you can determine structure and identification using these kind of methods.

Q. Can you use applied spectroscopy to determine the compounds in tobacco smoke?

A. Yes, that's correct.

Q. Explain for me then what chromatography is?

A. Chromatography takes a number of forms, but it's basically a method of separating a mixture of compounds into individual components. It can take the form of gas chromatography, which is where you vaporize materials, send them through a column. It contains an absorbant and you have a distribution of these materials in the absorbant as it moves down the column and this causes a separation.

So if you have a detector at the end of the column you can detect individual materials as they emerge. At the time they are in the column can be a characteristic of identification as well, but usually you take these separated materials and go to the spectroscopy or other methods to identify them. There is a similar method that deals with liquid materials called liquid, liquid chromatography, but it's overall a general technique for separation of mixtures into individual components.

Q. Is it possible to use chromatography to determine DNA strand mutation by virtue of exposure to chemical

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compounds?

A. A form of chromatography is used to separate the different DNA strands.

Q. Would it then be correct that you would need to use spectroscopy to determine whether exposure to a chemical compound induced the damage to a DNA cell?

MR. ALLINDER: Objection.

THE WITNESS: If you are trying to determine adducts, for example, which are formed between, say, compounds and DNA, there are a number of steps in the procedure to look for these adducts, but you need some sort of amplification to increase the concentration. But in this case, the mass spectroscopy would be the technique for trying to identify individual adducts.

BY MR. HEFTER:

Q. Within the past ten years, have you personally conducted any research using spectroscopy or chromatography to determine DNA or cell mutation by virtue of exposures to chemical compounds?

A. No, I have not worked in the laboratory in the last ten years.

Q. When was the last time you worked in the laboratory?

A. Probably in the 1970s, but I have been director of that kind of activity since the research division has

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reported directly to me through my whole career.

Q. Does the research division of Lorillard Tobacco Company report to you directly today?

A. No, it does not.

Q. Would it be fair to say that the research division of Lorillard Tobacco Company reported to you up until your retirement as the chief executive officer of the company?

A. That's correct.

Q. When did you take over as the head of research of Lorillard Tobacco Company?

MR. ALLINDER: Objection.

THE WITNESS: I became director of basic research in 1965 and director of research and development in 1967.

BY MR. HEFTER:

Q. Would it be fair to say that your responsibilities for direct -- personal and direct participation in the laboratory discontinued at or about the time that you became a senior vice president of operations and research in 1975?

A. Yes, although I was still very much involved in knowing exactly what was going on in the laboratory through that period.

Q. So after that time period --

A. I think after the time period where I became executive vice president I had less time spending in the laboratory.

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Q. Between 1979 to 1991 as the executive vice president of operations and research, was there a time that you spent no time in the laboratory?

A. Not during that period. When I became vice chairman I spent very little time in the laboratory.

Q. When you became vice chairman and chief operating officer in 1981, what percentage of your time, if you can recall, was spent in the laboratory?

A. When you say in the laboratory, I am saying I attended meetings and presentations by investigators. I did that less frequently. I don't think I stopped it. I continued to maintain awareness of the published literature through this whole period.

Q. I guess my question is, personal involvement in research?

MR. ALLINDER: Object to the form.

BY MR. HEFTER:

Q. I will follow it up with a question.

In terms of direct involvement in research, what percentage of your time was spent in the laboratory doing research in or about the 1991 time frame?

MR. ALLINDER: Object to the form.

THE WITNESS: Let me try to answer it this way. I think the main activity I had in the laboratory in that time had to do with fire research or fire, and I did not

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specifically conduct experiments, but I participated in the analysis of data that was generated in the laboratory relating to the susceptibility of various materials to smoldering combustion.

BY MR. HEFTER:

Q. If you turn, Dr. Spears, to the page that's right after your CV, which is the last two pages of your report.

A. I'm not sure I understand which page.

MR. ALLINDER: I'm not sure we have what you are talking about.

MR. HEFTER: Let's go off the record.

(Recess was taken from 10:33 a.m. to 10:47 a.m.)

MR. HEFTER: Let me mark as Spears Exhibit No. 2 a list of Dr. Spears -- purports to be a list of Dr. Spears' testimony for the past five years.

(Exhibit No. 2 marked for identification.)

BY MR. HEFTER:

Q. Dr. Spears, if you just take a minute to look down that list?

MR. ALLINDER: If you will take a look at this exhibit, it looks like the copy ink has cut off the bottom line on the exhibit that Dr. Spears has. My copy is the same way. Do you see what looks like a May 10th entry at the bottom of the first page?

MR. HEFTER: Yes.

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MR. ALLINDER: And it's not really legible on the witness' copy nor on mine. We can substitute a better copy later unless this is going to impede your examination. We can substitute in the record later today a better copy.

MR. HEFTER: Why don't we do that. If for the purposes of the examination we can just use that copy.

MR. ALLINDER: If you need to ask him a question about that entry we can do that, certainly. For your information, so that you can read your copy -- is your copy legible?

MR. HEFTER: My copy is legible and complete, I think, but I think for the witness' purposes he may want to have that in front of him.

MR. ALLINDER: If we need to make reference to it we'll do that.

MR. HEFTER: I think I will make reference to it, not that particular entry, but I want to find out from the witness if this is a complete and accurate list and he would need to see the bottom entry in order to testify to that.

MR. ALLINDER: That's fine. What we'll do is when we get to lunch we'll make sure there is a better copy made of this exhibit and you will substitute it in the record at that point. Is that okay?

MR. HEFTER: Yes, that's fine.

Dr. Spears, if you can -- have you had an

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opportunity to look down this list?

THE WITNESS: Yes, I have.

BY MR. HEFTER:

Q. Do you know if there is any case in which you have testified in smoke and health litigation from November, 1995 to the present that's not included on this list?

A. I do not believe so.

Q. Prior to November, 1995, did you testify at any smoking and health litigation in the United States?

A. Yes.

Q. How many times would you say you have testified prior to November, 1995 in smoking and health litigation?

A. I'm not sure. One comes to mind, which is the Cipollone case.

Q. Other than the Cipollone case, is there any other case?

A. It's possible, but I can't recall any others at the moment.

MR. ALLINDER: Michael, excuse me for a moment. I think there has been some testimony by Dr. Spears since the time of this expert report that's been provided and you might want to ask him about that specifically.

MR. HEFTER: Thank you. I will.

Let me close the loop on my prior line of questioning, which is, would it be fair to say that prior to

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November, 1995 your testimony was offered in individual smoker actions against Lorillard Tobacco Company?

MR. ALLINDER: Object to the form.

THE WITNESS: Prior to 1995?

BY MR. HEFTER:

Q. November, 1995.

A. If there were other -- if there was other testimony, I think it would have been related to the Kent filter, the Kent filter cases, but I don't really recall whether there was any prior to '95 or not.

Q. Would it be fair to say that prior to 1995 you did not testify at any third party medical care case against the tobacco industry?

A. That's correct.

Q. If you take a look at the last entry, which is June 16, 1999 on the exhibit, on page two. Since June 16, 1999 and other than sitting here today, have you testified in any smoking and health litigation?

A. This would be the Falise case, I guess.

Q. Other than Falise, is there any other case that comes to mind that you have testified in smoking and health litigation?

A. I don't believe so.

Q. When did your Falise deposition take place?

A. Several weeks ago.

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Q. Are you designated as an expert witness in the Falise case?

A. I believe so.

Q. In any of the cases listed on Exhibit No. 2, were you designated as an expert witness in any of these cases?

A. I believe the answer is yes, but I don't recall which I was a fact and which I was an expert.

Q. Let's break it down. In the Braun case, do you recall whether you were designated as an expert witness?

A. No, I don't.

Q. You don't recall one way or the other?

A. I don't recall one way or the other and that would be true I think of all of these.

Q. In any of these cases that are listed in Exhibit No. 2, do you recall preparing expert reports?

A. Yes.

Q. Do you recall --

A. Again, I don't remember the details as to which case.

Q. Have you prepared any expert report in the Falise case?

A. Yes, I believe so.

Q. If you recall, do you remember the general subject nature of your expert testimony in any of these cases that are listed in Exhibit No. 2?

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A. Well, generally, the expert testimony has been around the same subject material that's listed in this particular case. I can't remember in the Kent filter cases exactly what the expert witness covered.

Q. Is that a case where you recall being designated as an expert witness?

A. Well, it's a case that -- these are cases that relate to a product that Lorillard made in the 1950s, so much of my testimony is based on documents that I have reviewed, but again, I don't recall the specific designations in terms of expert and fact.

Q. You do know, however, that you have been designated as an expert witness in this case, BlueCross And BlueShield of New Jersey?

A. Yes, I do.

Q. Who contacted you to be an expert witness in this case?

A. It would have been our attorneys, internal attorneys.

Q. Do you recall specifically who contacted you?

A. I think Mr. Reilly.

Q. And Mr. Reilly was the first person to contact you to inform you that you would be designated as an expert witness in this case?

A. I believe that's correct.

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Q. Did Mr. Reilly inform you of the subject matter of your expert testimony at that time?

A. Yes, he did.

Q. What did he say?

A. I can't recall exact words, but to the effect that I would be testifying as an expert regarding the materials that are listed here in the document I had here, the expert report, and I reviewed that material in terms of the expert report after it was prepared.

Q. Who prepared the expert report?

A. I don't know. Mr. Reilly was the principal. Whether he actually prepared it or had assistance in preparing it, I don't know.

Q. Did you have any discussions with anybody at the Shook, Hardy firm about the content of your expert report which is Spears Exhibit No. 1?

MR. ALLINDER: Object to the form.

BY MR. HEFTER:

Q. Separate and apart from your preparation for your deposition today?

A. I don't believe so. I believe the primary and maybe there may have been some incidental discussion with someone at Shook, Hardy, but principally it was Mr. Reilly.

Q. How many conversations did you have with Mr. Reilly concerning the expert report which is Exhibit No. 1?

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MR. ALLINDER: Object to the form. Michael, are you asking him about the preparation of the report?

BY MR. HEFTER:

Q. I'm just talking about the preparation of the report at this time. Let me limit my questions now to that particular sequence of events.

A. I believe one or two, and then I reviewed the final version.

Q. Would it be fair to say that you personally didn't type up this document?

A. That's correct.

Q. Prior to reviewing a first draft of the report, did you contribute any language to the report to Mr. Reilly?

MR. ALLINDER: Object to the form.

THE WITNESS: I have changed statements in many reports that Mr. Reilly has given me. It's kind of lost in all of that as to whether I specifically asked for something to be changed in the draft of this report.

BY MR. HEFTER:

Q. I'm not talking about the changes in the draft. I'm talking about prior to the time that you first saw a draft of Spears Exhibit No. 1, did you provide Mr. Reilly with any substantive comments about what you wanted to be in your report?

MR. ALLINDER: Object to the form.

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THE WITNESS: We had discussions to what I would be testifying about before this was prepared. I can't recall comments that I specifically made.

BY MR. HEFTER:

Q. You testified before that you made some changes to various reports that Mr. Reilly has given you over time?

A. Yes.

Q. Do you recall any specific changes that you made to this particular report?

A. I do not.

Q. How many hours did you work on this report, which is Exhibit No. 1?

MR. ALLINDER: Object to the form.

THE WITNESS: I don't think I spent more than an hour or so.

BY MR. HEFTER:

Q. Since the preparation of the report which is Exhibit No. 1, have you spent -- and other than in preparation for your deposition, have you spent any other time working on the BlueCross And BlueShield of New Jersey case?

A. No, I have not.

Q. You prepared for your deposition by meeting with counsel yesterday, is that correct?

A. That's correct.

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Q. Prior to yesterday, have you met -- did you meet with counsel in preparation for your deposition today?

A. I don't recall that I did.

Q. Who was present at your preparation session yesterday?

A. The three who are here, Mr. Reilly, Ms. Clark and Bill Allinder.

Q. There was nobody else present?

A. No, there wasn't.

Q. How many hours did you meet with those three individuals yesterday?

A. We met from about 9:30 in the morning until 3:15 in the afternoon with some break for lunch.

Q. In preparation for your deposition, did counsel show you any documents?

A. Yes.

Q. Other than your expert report, can you recall what those documents were?

A. I can recall some of the documents, yes.

Q. Can you describe them for me?

A. There were documents that were related to -- first of all, I was copied on the documents and they were documents related to discussions between Lorillard, CNA and The Tobacco Institute regarding premiums, reduced premiums for non-smokers.

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Q. How many documents, if there were more than one, dealt with the issue of non-smoker premium differentials and discussions between Lorillard, CNA and The Tobacco Institute?

MR. ALLINDER: That he looked at yesterday?

BY MR. HEFTER:

Q. That you looked at yesterday?

A. I didn't count them, but I would guess maybe a dozen.

Q. Other than that subject area, do you recall reviewing documents related to other subject areas yesterday during your preparation session?

A. There were other documents, but I don't recall them at the moment.

Q. In the cases that are listed in Spears Exhibit No. 2, it indicates that you have been -- you testified at deposition a number of times, is that correct?

A. That's correct.

Q. Would it be fair to say then in all those instances you have been represented by the Shook, Hardy firm?

MR. ALLINDER: Object to the form.

THE WITNESS: I think that would be the case, yes. There may have been other representations, though. I should say additional representation.

BY MR. HEFTER:

Q. When you say "additional representation," you mean

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there may have been more than one law firm who was representing Lorillard Tobacco Company in these particular cases?

A. Yes, that's right.

Q. You indicated earlier that you reviewed approximately, and the record will speak for itself, I don't want to put words in your mouth, approximately 100 scientific articles from January 1st of this year to the present. Do you maintain a file of those articles?

A. I have a file, yes.

Q. And those files are contained in an office that you maintain at Lorillard Tobacco Company?

A. I have a current file, yes, and then there are probably many reprints that I reviewed which are in our document storage area.

Q. You testified or your CV indicates that you published a number of articles, and it's on page six of your CV. You published a number of articles while you were employed by Lorillard Tobacco Company?

A. That's correct.

Q. Do you need to seek prior approval of your superiors in order to publish these articles?

A. I did when I first joined Lorillard in that I reported to someone in the research organization and they would review articles and certainly comment and indicate

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whether they thought they were publishable articles.

Q. Did you ever submit an article for review to your superiors at Lorillard that was recommended that you not publish them?

A. No.

Q. Would it be fair to say that every article that you wanted to publish while you were employed by Lorillard Tobacco Company was, in fact, published?

A. That's correct.

Q. It indicates on page two of your CV that you received a distinguished achievement award in Tobacco Science, Philip Morris, 1970. I will give you a minute to get there.

MR. ALLINDER: Mike, where does that appear on the page?

BY MR. HEFTER:

Q. If you look under professional memberships and honors, right in the middle.

A. That's correct.

Q. What did you receive that award for?

A. This was an award that Philip Morris initially started and was given to young investigators who had made significant contributions to the subject of tobacco and science. I can't remember, I was maybe about the third or fourth recipient of this award which occurred annually and

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continues to occur today.

Although I think other organizations may have joined in with Philip Morris, so it may not be called the Philip Morris award today.

Q. Was there a particular piece of research that you were -- that you had conducted that caused you to receive this award?

A. I think it was for my publications relating to selected filtration of phenolic compounds.

Q. That was selective, I'm sorry, filtration?

A. Selective filtration of phenolic compounds from tobacco smoking.

Q. Is there an individual within Lorillard who recommended that you receive that award?

A. I don't know.

Q. If you turn to page two of your expert report. Throughout your report on page two, three and four, you state on a number of occasions that you may testify about certain areas in this case, is that correct?

A. That's correct.

Q. Have you had any discussions with counsel about what you will be testifying about in this case?

MR. ALLINDER: Object to the form.

THE WITNESS: Nothing beyond what is here.

BY MR. HEFTER:

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Q. If you look at the last paragraph on page two, which is really the carryover paragraph.

A. Right.

Q. If you can just take a second to read that paragraph.

A. Yes.

Q. Does this paragraph contain any expert opinion regarding Lorillard's historical awareness of reports regarding a relationship between smoking and health?

MR. ALLINDER: Object to the form.

THE WITNESS: I think it would include the work that Lorillard has done in their laboratory on the same subject.

BY MR. HEFTER:

Q. But does the report include an opinion?

A. Does it include an opinion?

MR. ALLINDER: Same objection.

THE WITNESS: It would include an opinion as to the relevance and significance of some of the findings.

BY MR. HEFTER:

Q. Where is that opinion -- where is an opinion stated in that paragraph?

A. If I were asked an opinion I would give it.

Q. But the opinion is not stated in this paragraph, is that correct?

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MR. ALLINDER: Object to the form.

THE WITNESS: No, it's not.

BY MR. HEFTER:

Q. Turn to the next paragraph, please, and if you could, take a minute to read that paragraph.

A. Yes.

Q. Is there an opinion one way or the other on any matter relating to Lorillard's in-house research relating to the chemical composition of cigarette smoke contained in that paragraph?

MR. ALLINDER: Object to the form.

THE WITNESS: No, it doesn't. My answer would be the same, if I'm asked an opinion I would give it.

BY MR. HEFTER:

Q. But the same answer holds through, this report does not contain an opinion one way or the other?

MR. ALLINDER: Object to the form.

THE WITNESS: It doesn't say that, no.

BY MR. HEFTER:

Q. If you turn to the next paragraph, please.

A. Yes.

Q. Take a minute to read that paragraph.

A. Yes.

Q. Have you had an opportunity to read it?

A. I have.

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Q. Is there an opinion stated one way or the other on any matter relating to cigarette design and the reduction of tar and nicotine levels in cigarettes in the past several decades contained in that paragraph?

MR. ALLINDER: Object to the form.

THE WITNESS: I think it's implied that it would be my opinion in designing cigarettes that Lorillard has responded to scientific and public health concerns, and I would read that into that.

BY MR. HEFTER:

Q. But that's not expressly stated there, is it?

A. No, it says I may testify about this.

Q. But it doesn't contain an expert opinion one way or the other?

MR. ALLINDER: Object to the form.

THE WITNESS: It doesn't say those words, if that's what you are asking.

BY MR. HEFTER:

Q. Turn to the next paragraph, please.

MR. ALLINDER: Which one are we up to now?

MR. HEFTER: The third full paragraph on the page.

MR. ALLINDER: The one dealing with the tobacco work?

MR. HEFTER: Correct.

THE WITNESS: Yes, it says I will offer my expert

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opinion --

MR. ALLINDER: There is no question pending.

THE WITNESS: Sorry.

BY MR. HEFTER:

Q. Is there -- other than your statement that you may offer your expert opinion, is there an expert one way or the other about the National Cancer Institute's tobacco working group that's contained within this paragraph?

MR. ALLINDER: Object to the form.

THE WITNESS: I'm not sure I understand your question. The paragraph says what it says.

BY MR. HEFTER:

Q. Correct, and my question is whether there is an expert opinion that's contained within this paragraph?

MR. ALLINDER: Same objection.

THE WITNESS: The opinion is not there, no.

MR. HEFTER: Bill, I'm going to state for the record that we believe that the expert disclosure if Dr. Spears is going to be offered as an expert is deficient under Federal Rules of Civil Procedure, 26.

I will continue with my examination, but there is really no basis for me to conduct an expert deposition of Dr. Spears based on this expert report.

MR. ALLINDER: Well, Dr. Spears has had been made clear, I think both in the expert report and in prior

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communication both with plaintiffs' counsel and the court as principally a fact witness.

However, Dr. Spears may offer opinions on subjects relating to the areas that are outlined in his expert report because he has the competence and he has the ability to offer opinions on a variety of subjects, but principally his testimony that is intended to be offered in this case is going to be of a factual nature and the expert report, I think, is clear in stating that.

And as well as I indicated before, prior communications with plaintiffs' counsel and the court have indicated that Dr. Spears is principally a fact witness. He is designated, however, as an expert because he may be called upon to offer opinions in the case. If you wish to proceed with the examination, this expert deposition, because that's the way it's noticed, you can certainly proceed to inquire of Dr. Spears about what his opinions are on the subjects that are outlined in his expert report.

MR. HEFTER: I understand that and I think you understand what my position is here that under rule -- if Dr. Spears will be offered as an expert witness at trial, then I'm entitled now to know what his opinions are and the basis for those opinions which are not contained in the report.

MR. ALLINDER: I understand your position and my statement to you is that you have the opportunity today to

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inquiry of Dr. Spears as to what his opinions are on the subjects that are outlined in this expert report, and you, of course, will choose to proceed or not choose to proceed, and then we can decide, I suppose, if it becomes an issue as we get closer to trial as to whether he will, in fact, be permitted to offer opinion testimony on these subjects.

MR. HEFTER: Well, I'm going to continue with my examination of Dr. Spears because we are here, but it's certainly without waiver of my right to re-depose Dr. Spears at a later point if he will offer expert opinion testimony at trial, and I believe that if that's the case that we are entitled to know that prior to the close of the fact discovery or expert discovery in this case.

MR. ALLINDER: I didn't understand your last statement. You are entitled to know what?

MR. HEFTER: Whether Dr. Spears will be offering expert opinions and what those opinions are and the basis for his opinions prior to the close of expert discovery in the case.

MR. ALLINDER: I understand your position and you are certainly entitled to proceed with your examination today without waiver of your position, and likewise, in permitting you to proceed with your examination, defendants are certainly not waiving or Lorillard is not waiving its position concerning the adequacy of this report and the

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opportunity that plaintiffs have today to examine Dr. Spears fully regarding the opinions that he might be asked to offer at trial.

So on that basis we certainly can proceed.

MR. HEFTER: I understand. If I can just ask that we take a two or three minute break.

(Recess was taken from 11:21 a.m. to 11:32 a.m.)

MR. ALLINDER: Dr. Spears, when we were on break you indicated to me that there were two answers in your prior testimony that you needed to supplement. Mr. Hefter was asking you about cases in which you had testified either at deposition or at trial since June of 1999. Do you recall that question?

THE WITNESS: Yes, I do.

MR. ALLINDER: And are there cases in which you have testified since June of 1999 that you did not include in your prior answer?

THE WITNESS: Yes, there is. There is one trial case referred to as Carlson, which took place in Duluth, Minnesota.

MR. ALLINDER: Dr. Spears, would you take a look at Spears Exhibit No. 1, please, and look at page two of your CV.

In the paragraph concerning related activities, do you recall the question from Mr. Hefter about whether --

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about federal regulatory or legislative hearings at which you had testified?

THE WITNESS: I do.

MR. ALLINDER: Do you have additional hearings at which you testified that you did not include in your prior answer to Mr. Hefter?

THE WITNESS: Yes, I didn't realize that the so-called Waxman hearings were not on here.

MR. ALLINDER: Are there any others?

THE WITNESS: No, that's all.

MR. ALLINDER: Thank you, Michael.

MR. HEFTER: Thank you.

MR. BROWN: And if I may, for the record, make a quick statement on behalf of the plaintiffs for The National Asbestos Workers case. For the record, Brian Brown, and I would say that we would concur with the position taken by counsel for BlueCross BlueShield concerning the insufficiency of Dr. Spears' expert disclosure in The National Asbestos Workers case, as well as they appear to me to be similar in form and substance.

MR. ALLINDER: For Lorillard I have, of course, the same position that I outlined before on the record and without taking up a great deal of time at the deposition today going through the various pieces of communication and information available to plaintiffs' counsel, both from

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BlueCross And BlueShield, and The National Asbestos Workers concerning Dr. Spears' intended expert testimony, I will note for the record that there has been extensive transcripts of depositions provided to plaintiffs' counsel in this case in which Dr. Spears' expert opinions have been examined by plaintiffs' counsel in other litigation.

BY MR. HEFTER:

Q. Dr. Spears, the testimony that was provided in Duluth in relation to the Carlson case, was that in deposition or trial testimony?

A. That was trial testimony.

Q. Did you testify as an expert witness in the Carlson case, as far as you know, or you can recall?

A. Again, I don't recall.

Q. Do you know if the Carlson case was or is pending in federal or state court in Minnesota?

A. It was state court.

Q. Did you prepare an expert disclosure in the Carlson case, to the best of your recollection?

A. I don't recall.

Q. When was your trial testimony in Carlson?

A. About a month ago.

Q. You testified that you testified before the Waxman hearings in 1994, is that correct?

A. That's correct.

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Q. Do you recall the CEOs of various tobacco companies testifying that cigarette smoking is not addictive?

MR. ALLINDER: Object to the form.

THE WITNESS: Yes, I have seen that testimony or heard it, yes.

BY MR. HEFTER:

Q. And you know that a number of CEOs were -- strike that.

Did you appear as a representative of Lorillard Tobacco Company when asked by the house committee whether smoking was addictive?

MR. ALLINDER: Object to the form.

THE WITNESS: I was present at that session, yes.

BY MR. HEFTER:

Q. Was there a representative of Lorillard Tobacco Company at those hearings you testified that smoking is not addictive?

MR. ALLINDER: Object to form.

THE WITNESS: Yes, I believe Andrew Tisch did.

BY MR. HEFTER:

Q. Did you confer with Mr. Tisch prior to his testimony that smoking is not addictive?

A. I don't believe that was his testimony. I think in terms of prepared testimony, I think it was a question that was asked by Waxman.

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Q. And in connection with that question that was asked by Congressman Waxman, did you meet with Mr. Tisch or confer with Mr. Tisch prior to that session in Congress that day?

MR. ALLINDER: Object to the form.

THE WITNESS: I had discussions with him regarding testimony, but I don't remember specifically that question being considered.

BY MR. HEFTER:

Q. And you believe that Mr. Tisch was testifying accurately and truthfully to the Waxman committee on that day?

A. Yes, I do.

Q. Do you know who Steven Parrish is?

A. Yes, I do.

Q. Have you ever met Mr. Parrish before?

A. Yes, I have.

Q. Do you know Mr. Parrish has stated in the past few weeks that cigarette smoking is addictive?

MR. ALLINDER: Object to the form.

THE WITNESS: No, I don't know what his statements have been in the last few weeks.

BY MR. HEFTER:

Q. Have you read any news articles in which Mr. Parrish has commented on the addictiveness of cigarette smoking one way or the other?

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A. I do not recall having read them.

Q. Do you know that Philip Morris' public position on the addictiveness of smoking today as reported at the press is that cigarettes are an addictive drug?

MR. ALLINDER: Object to the form.

THE WITNESS: They are an addictive drug?

BY MR. HEFTER:

Q. Correct.

A. No, I'm not aware of that testimony.

Q. You are not aware that that's Philip Morris' public position today?

MR. ALLINDER: Let me stop you for a moment. Will you give me a continuing objection with respect to the accuracy of either testimony or public statements that you are representing Dr. Spears as part of your questioning today?

MR. HEFTER: No. I may, but let me try to get at it a different way.

MR. ALLINDER: I will continue to make my objection then.

MR. HEFTER: Mark this as the next exhibit.

(Exhibit No. 3 marked for identification.)

MR. HEFTER: I would like to mark this as Exhibit No. 3, but I only have one copy, Bill.

MR. ALLINDER: Can I take a look at it before you

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hand it to the witness?

MR. HEFTER: Sure.

MR. ALLINDER: Did you intend to hand it to the witness?

MR. HEFTER: I intend to hand it to the witness.

Before I show it to the witness, let me just make sure -- I will show this to the witness, Spears Exhibit No. 3.

THE WITNESS: Do you want me to read it?

BY MR. HEFTER:

Q. If you can read the article. Just for the record, it's an article appearing in the Washington Post, and I can give you the date in a minute, but in all fairness, it's a printout from Westlaw or Lexis?

MR. ALLINDER: Michael, we'll see how this goes. If I think I can proceed without having a copy in my hand as you are asking questions, we'll do that, but if I think we need one we'll have to stop.

MR. HEFTER: It makes sense to me to stop and get a copy. I will note it took quite a bit of time to get copies made the last time. I don't want to have another 15 minute break here.

MR. ALLINDER: You can go at it as you choose. I think we need to have the copies. If you want to get the copies now, let's walk out and get them.

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(Recess was taken from 11:45 a.m. to 11:51 a.m.)

MR. HEFTER: Thank you, Bill, for providing the copies.

Let me note for the record that the article which is now Spears Exhibit No. 3 is an article appearing in the Sunday March 5, 2000 edition of the Washington Post.

Dr. Spears, prior to the break did you have an opportunity to read Spears Exhibit No. 3.

THE WITNESS: Yes, I scanned it.

BY MR. HEFTER:

Q. And what I would like to refer you to is on the second page of the exhibit, Mr. Parrish's comment, and I will read it into the record, which appears towards the end of his remark there. So I want to sit down and talk to you, obviously, and a lot of other people about what is the regulatory regime for tobacco, not as a pharmaceutical or a medical device, but as a tobacco product -- which is addictive. I have conceded that, and which causes harm to some people.

Do you see where I'm reading?

A. No -- yes, I see it.

Q. Let me reiterate my previous question. First of all, let me ask, have you ever seen this article before?

A. No, I have not.

Q. Have you ever seen any article in which it is

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referenced that Mr. Parrish has said that tobacco products are addictive?

A. Maybe, I don't recall.

Q. Within the past few weeks, have you read any newspaper articles reporting on Mr. Parrish's comments in the Washington Post?

A. No, I have not seen reference to these comments.

Q. Have you seen any newspaper article which has referenced Philip Morris' position that tobacco products are addictive within the past several weeks?

MR. ALLINDER: Object to the form.

THE WITNESS: I don't recall that.

BY MR. HEFTER:

Q. Do you agree with Mr. Parrish that tobacco products are addictive?

A. It depends on the definition one uses. I think there are three definitions and probably the one in the public is a common definition where they refer to most things that are pleasurable as addictive, from reading to gambling to what have you.

It's commonly referred to as addictive and certainly under that kind of a definition you could call cigarettes addictive. Under a more scientific definition, I think there are two. One was the definition that existed and was used prior to about 1980, which included the criteria of

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intoxication and a criterion of significant withdrawal effects. Those are not really present with regard to smoking cessation and/or smoking. I'm talking specifically intoxication. There is no intoxication.

If you change the definition to one that's in the DMS IV now, which is a range of dependence, I guess from zero to heavily dependent nicotine can fit on that scale and if you use addiction to be synonymous with dependence, then you could call it addictive under that definition as well.

But I think there are two important points. One, nicotine does not have the property of a classic so-called hard drugs. It does not have these properties, and secondarily, if you decide to quit smoking you certainly can make a decision to do it, millions of people have. I also quit smoking. So regardless of what you call it, I think that's the important issue.

Q. Has Lorillard ever made any public statement that smoking is addictive no matter how you define it, using that term, addictive?

A. I don't believe Lorillard has made any published statements one way or the other other than that Waxman hearing that you referenced.

Q. So the Waxman hearing is the only time an official of Lorillard Tobacco Company has ever made a statement that smoking is addictive one way or the other?

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MR. ALLINDER: Object to the form.

THE WITNESS: Well, I can't be sure throughout history that no one ever made such a statement, but to my knowledge, I'm not aware of statements of that nature.

BY MR. HEFTER:

Q. Are you aware that public health authorities have categorized nicotine as a drug similar to a heroin or cocaine?

A. Yes, and I think this is obviously not correct in the sense that there is no intoxication with nicotine. You can reason, you can function, carry out your duties. You can't if you are taking doses of cocaine.

Q. The withdrawal symptoms of cessation of heroin, do you know that there are assertions in scientific literature which claim that the withdrawal symptoms for nicotine withdrawal and heroin withdrawal are similar?

A. I have seen those assertions, but here again, the withdrawal symptoms associated with cocaine and other hard drugs can be life threatening, require hospitalization and so forth. That's not true with nicotine. The classic withdrawal symptoms of nicotine are irritability, increased appetite, rather minimal kinds of effects.

Q. So your position today is that smoking is not addictive as defined by DMS IV?

MR. ALLINDER: Object to the form.

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THE WITNESS: No, that's not what I said. I said if you use a DMS IV definition and refer to dependence as addicting, then you would refer to it as addicting under DMS IV, but it does not have the properties of the hard drugs that you call addictive as well.

BY MR. HEFTER:

Q. You indicated that under the definition of -- under DMS IV that there are ranges of dependence?

A. Yes.

Q. What range does nicotine dependence fall into?

A. Well, it's certainly not up on the scale with the hard drugs that we are referring to. It's more on the scale with things like caffeine.

Q. Is your current position today that nicotine is not addictive as defined -- as that term is defined by the Surgeon General of the United States?

MR. ALLINDER: Object to the form.

THE WITNESS: No. The Surgeon General changed the definition in 1980 and under the new definition you would call it addicting or I should say the Surgeon General changed the definition that has been used throughout the reports from the early reports to after 1980.

BY MR. HEFTER:

Q. Do you know how Mr. Parrish used the term addictive in the Washington Post article, which is Exhibit No. 3?

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A. No, I don't. I don't think there is a discussion of how he is using the term in terms of a definition.

Q. But you don't know one way or the other how he is using that term?

A. No, I have not seen the article prior to this.

Q. You haven't had any discussions with him regarding his statements?

A. I have not.

Q. Do you believe that individuals who stop smoking suffer from withdrawal symptoms?

A. From the type that I just mentioned I think it's typical withdrawal symptoms.

MR. ALLINDER: Can I ask you for a clarification, please. You have been using the word you in some of your questions. Are you asking Dr. Spears whether he has expert opinions on these subjects that he intends to offer at trial? Are you referring to whether he has expert views on the subject or are you asking about whether there is a Lorillard public submission on these?

MR. HEFTER: I'm asking him actually the latter, whether there is a Lorillard public position and what his position is as the chairman, director of Lorillard is. As you stated earlier Mr. Spears may or may not be, but he is likely to be a fact witness in the case, and I'm basically asking him what his views are as chairman of the board of

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Lorillard Tobacco Company.

MR. ALLINDER: This is an expert deposition, too.

MR. HEFTER: My understanding, Bill, is that I'm not limited in terms of asking him questions as a fact witness or as an expert witness.

MR. ALLINDER: That's not my understanding because the notice in both the BlueCross And BlueShield case and in the cross notice in The National Asbestos Workers case are notices for Dr. Spears' expert deposition.

Now, having said that, on the other hand we have not reached the point where I am going to object to your examination on that basis, and I don't believe up to this point in time I have made an objection on the record that your examination has really exceeded the bounds of the notice, and I'm not sure that I will, depending on what you inquire about, but I do note this is an expert deposition per your notice.

MR. HEFTER: Well, that being said, again I don't know if I'm limited there. However, in his expert report Dr. Spears does say he may be asked to comment on the opinions expressed by other witnesses in this case, which leads his testimony wide open as to any one of our experts, and as you know, we do have addiction experts. So to the extent Dr. Spears would be coming in to comment on those expert witnesses, then certainly I believe I'm entitled to ask him

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these questions here.

MR. ALLINDER: Without agreeing or disagreeing with you on that point, as I said before I have not made an objection that you exceeded the scope of notice at this point in time, and it's quite likely I will not make an objection on that basis, but my only point for clarifying or asking for clarification of the question earlier was to make sure that the record was clear as to what it was that you were asking Dr. Spears to comment about.

MR. HEFTER: I understand that.

Would you consider yourself, Dr. Spears, to be an expert on addiction.

THE WITNESS: No, I am not an expert in addiction. I think I am knowledgeable.

BY MR. HEFTER:

Q. Have you ever conducted research into the efficacy of nicotine patches or gum?

A. No, I have not.

Q. Have you ever conducted research exploring the addictive properties of nicotine?

A. No, I have not.

Q. As the chairman of Lorillard Tobacco Company, do you believe that the federal government should regulate tobacco products?

A. They already do.

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Q. Do you believe there should be additional regulations over and above what the federal government does today?

MR. ALLINDER: Object to the form.

THE WITNESS: I think it depends specifically what one is talking about. I haven't considered what I think the government should do beyond what they do now.

BY MR. HEFTER:

Q. Do you believe there should be additional restrictions on advertising?

A. I think the advertising is very restricted now.

Q. Do you believe there should be restrictions over and above advertising that there is today?

MR. ALLINDER: Object to the form.

THE WITNESS: I don't think so. I think there are already severe restrictions on advertising.

MR. HEFTER: Let's go ahead and change the tape.

(Recess was taken from 12:06 p.m. to 12:07.)

MR. HEFTER: Let's mark for the record Spears Exhibit No. 4.

(Exhibit No. 4 marked for identification.)

MR. ALLINDER: Before you ask a question, can you give me one second to check a document. I want to put a privilege objection on the record.

MR. HEFTER: I assumed you would. Do you want to

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make a statement now or that was your putting it on the record?

MR. ALLINDER: Yes, I'm noting for the record the privilege objection that one or more of the defendants may have with respect to this document and we, counsel in this room, I think are all aware of the order that has been entered - the orders that have been entered in these cases concerning the use of privileged documents at depositions and we are proceeding pursuant to provisions of those orders.

MR. HEFTER: Thank you, and your objection is noted.

MR. ALLINDER: Thank you.

BY MR. HEFTER:

Q. Dr. Spears, have you seen this document before?

A. I don't think so.

Q. If you turn to the last page, page four of the document.

A. Yes.

Q. It indicates in the bottom Arthur J. Stevens.

A. Yes.

Q. Who is Arthur J. Stevens?

A. He was a former vice president and general counsel for Lorillard.

Q. He is no longer the vice president and general counsel of Lorillard Tobacco?

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A. He is retired.
Q. When did he retire, if you know?
A. End of last year.
Q. That's 1999?
A. That's correct.
Q. The first page indicates American and other companies dismayed at direction of CTR research.
Do you know if on or about or in and around March, 1978 Lorillard's was dismayed a direction of CTR research?
A. I remember from time to time discussions of CTR and CTR's research.
Q. Do you recall in or around 1978 time frame Lorillard being dismayed at the direction of CTR research?
A. I think from time to time Lorillard was critical in the sense of whether there ought to be additional research and the types of research, contract versus grant activities. I don't remember the specific time periods, but from time to time we had -- questions were raised, yes.
Q. Isn't it true that some of the questions that Lorillard raised with respect to CTR research was criticism that CTR researchers were determining causation between smoking and various forms of cancer?
MR. ALLINDER: Object to the form.
THE WITNESS: That statement is here in the first paragraph, but I don't recall that being a Lorillard

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position.

BY MR. HEFTER:

Q. Do you know who Gardner and Kreisher were or are in the document?

A. I believe they were at the, Gardner was the scientific director of the Council for Tobacco Research and Kreisher was a member of the staff.

Q. Were you privy to any discussions with Mr. Stevens in or around 1978 regarding criticisms of CTR in the sense that is reflected in the first paragraph of this exhibit?

MR. ALLINDER: Object to the form.

THE WITNESS: No, I don't recall any discussions that I had with Mr. Stevens regarding the first paragraph.

BY MR. HEFTER:

Q. You indicated before criticisms regarding grant researches versus its own research --

A. Contract.

Q. Contract. Wasn't it true that the reason why Lorillard Tobacco Company had levelled these criticisms was because Lorillard wanted to create the impression to the public that CTR was independent and that the only way you could do that is if they were doing research through proposed grants?

MR. ALLINDER: Object to the form.

THE WITNESS: I think that was part of the

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discussion. On the other hand, I think there is some confusion over the word contract. Some people perceive contract to mean that you are defining what the research will be, and that takes away independence, the body that you are funding. That is true, but on the other hand there are certain things you can't get done under a grant, for example, the construction of the smoking machine and some mega scale experiments that require kind of an institution or a large organization rather than individual guarantee to conduct.

So I think the debate was confused by people's different definitions of what they thought the term contract research means.

Q. From 1990 to 1999 you were on the executive board of CTR?

MR. ALLINDER: Objection to form.

THE WITNESS: What period?

BY MR. HEFTER:

Q. 1990 to 1999.

A. Yes, I was on the board of directors.

Q. During your tenure on the board of directors -- strike that.

It's also true that CTR is no longer in existence, is that correct?

MR. ALLINDER: Object to the form.

THE WITNESS: It's no longer an organization

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carrying grants, administering grants. I think there is still a bit of an organization there that I guess relates to legal activities, cases they may be involved in.

BY MR. HEFTER:

Q. But as far as you know, CTR does not conduct any research either by contract or grants, to this day?

A. That's correct, that's all shut down.

Q. And do you know who pays CTR's legal fees in these cases that you are referring to?

A. It would be the membership of CTR in the past.

Q. And the membership of the CTR in the past includes the tobacco manufacturers or defendants in this case?

MR. ALLINDER: Object to the form.

THE WITNESS: That's correct.

BY MR. HEFTER:

Q. Has the membership in the past included any entity other than the U.S. tobacco manufacturers?

A. I don't believe so.

Q. If you turn your attention to the third paragraph of the document.

MR. ALLINDER: Still on page one?

BY MR. HEFTER:

Q. Still on page one. There is a reference there to SAB. Do you know what that refers to?

A. Yes.

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Q. Can you identify that for me?
A. Scientific advisory board.
Q. Were you on the scientific advisory board in 1978?
A. No.
Q. Have you ever been on the scientific advisory board to CTR?
A. No, no one from the industry has been on that board.
Q. Who decides who gets to become a member of the scientific advisory board?
A. The board itself and the scientific director.
Q. And who decides who the scientific director is of CTR?
A. The scientific director is hired by the membership, I guess, or a search committee.
Q. Does the board of directors determine -- the board of directors of CTR, do they determine who the members of the SAB will be?
A. No, they do not.
Q. It's solely determined by the scientific director, is that correct, and the SAB members?
MR. ALLINDER: Object to form.
THE WITNESS: That's right, the other members.
MR. ALLINDER: Michael, question of clarification, the questions you were asking, do they pertain to the time

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frame of this document or the entire period of CTR's existence?

MR. HEFTER: My question just for clarity of the record was in or around 1978.

MR. ALLINDER: Thank you.

BY MR. HEFTER:

Q. At least that's what I was intending to ask. The description of the selection of SAB members, would that be true for the entire period of CTR's existence?

A. I believe it would.

Q. If you turn to the next page -- I'm sorry, the next paragraph, which starts in January of 1977. There would start to be an agreement (C/C) that promotive carcinogenic experiments were not to proceed until whole smoke work completed. Do you know what C/C refers to?

A. No, I do not.

Q. Is it possible that C/C refers to committee of counsel?

MR. ALLINDER: Object to the form.

THE WITNESS: I don't know what it refers to.

BY MR. HEFTER:

Q. Do you know what whole smoke work refers to in that sentence?

A. Generally, yes.

Q. Can you tell me generally what your recollection of

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whole smoke work was in 1978?

A. Whole smoke means I think what comes from the end of a cigarette.

Q. Do you know what the whole smoke work is referred to in this document?

A. No, I don't.

Q. If you turn to the next page. If you look at point three, it refers to -- why don't you take a second or two to read it.

A. I have read it.

Q. It refers to Abood, do you see that?

A. I do.

Q. Do you know what Abood refers to?

A. Yes, I do.

Q. Can you tell me what Abood refers to?

A. He was an investigator, was a CTR grantee, as I recall, and as indicated here he came to Lorillard back in this time frame and made a presentation.

Q. Do you recall Mr. Abood making a presentation to Lorillard during that time frame?

A. I did not attend it, but I do recall he came to the research center and made a presentation concerning his work.

Q. Would it be fair to state that Mr. Abood had included concluded based on his research that nicotine had a physiological affect on the central nervous system?

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A. His work was with animals, and as I recall, he characterized a particular behavioral syndrome in animals that resulted from nicotine which had not been recognized up to that point.

Q. Do you know what the particular syndrome was, if you recall?

A. I can't remember exactly how the animals behaved, but it was a behavioral response.

Q. Do you know if Mr. Abood's research in that area was ever published in the scientific literature?

A. I believe it was.

Q. It refers to going beyond health mandate of CTR. Do you see that?

A. I see that.

Q. Do you know what that refers to?

A. I think it's raising the question as to whether or not this was getting to product development areas that could involve antitrust.

Q. Your answer there, is that based on speculation of what you believe happened or do you have personal knowledge of what Mr. Stevens meant by what he said --

A. Those are the general discussions I recall at the time.

MR. ALLINDER: Object to the form.

BY MR. HEFTER:

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Q. Did you have discussions with Mr. Stevens regarding whether CTR was going beyond its health mandate?

A. With respect to nicotine and the central nervous system?

Q. Correct.

A. And product development, yes.

Q. And what were your discussions?

MR. ALLINDER: Stop right there.

Your question as phrased asks in an unrestricted way for Dr. Spears to recount all of his discussions with Mr. Stevens pertaining to the subject area.

MR. HEFTER: I don't want to cut you off, but maybe I can try to rephrase it. It may not help you, but --

MR. ALLINDER: It may not help me. It may not help you, but at the moment I'm struggling whether you are going a little bit too far with your question, so we'll take another shot at it.

MR. HEFTER: I understand. Can I have Dr. Spears' last answer read back, please.

(The record was read.)

BY MR. HEFTER:

Q. Let me see if I can do this again. I believe you testified, Dr. Spears, that you believe sitting here today that you had general discussions with Mr. Stevens regarding the question whether CTR was going beyond its health mandate

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in or around 1978, is that correct?

A. I don't know whether I had discussions about going beyond the health mandate. I had discussions that related to their studies of nicotine, the central nervous system and whether or not this was product development kind of work.

Q. If you turn to the next page. On the top it says rationale by Ford prepared?

A. Yes.

Q. Do you know who Ford is?

A. Ford was a staff member at the Council for Tobacco Research.

Q. Was Dr. Ford, to your knowledge, asked to prepare a counter to Dr. Abood's work?

MR. ALLINDER: Object to the form.

THE WITNESS: I do not know.

BY MR. HEFTER:

Q. Do you know if Dr. Ford or Mr. Ford prepared any documents in or around this time frame?

A. I do not know, and I do not recall ever seeing anything from Ford in this.

Q. If you turn to the page three at the bottom where it says Yeaman statement at Boca Raton?

A. Yes.

Q. Then on the next page there is a question, do we want a CTR?

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A. Yes, I see that.

Q. Do you recall any discussions with Mr. Stevens or anybody else in or around the 1978 time frame which related to a phasing out of CTR?

A. I recall questions about CTR, whether it should continue, whether it should be something else, general kind of questions that you would raise about any organization that's had a long history, whether it was -- whether it should continue, whether it should become something else. Yes, we have had those discussions.

Q. In or around 1978, do you recall if any protocol or CTR's operating procedures were changed in any way as a result of discussions that are reflected in Exhibit No. 4?

MR. ALLINDER: Object to the form.

THE WITNESS: I am not aware of any changes at CTR that took place. As I say, there were discussions that relate to grant versus contract, and they may have clarified, I guess, what CTR would do with respect to contracts, but here again, they all went through the scientific advisory board.

BY MR. HEFTER:

Q. At this point in time, was CTR instructed not to go into any particular area of research regarding smoking and health?

MR. ALLINDER: Object to the form.

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THE WITNESS: Not regarding smoking and health, but I think they were instructed not to pursue the nicotine central nervous system, for the reason I gave.

BY MR. HEFTER:

Q. In reviewing your expert reports -- your expert report, I do not see any reference that you may testify about research conducted by CTR. Is that an accurate description of your summary of opinions that's contained in your expert report which is Exhibit No. 1?

MR. ALLINDER: Object to the form.

THE WITNESS: Would you repeat that again, please.

MR. HEFTER: Can I have it read back, please?

(The record was read.)

BY MR. HEFTER:

Q. Do you understand my question?

A. I understand your question. Yes, I think that's accurate.

Q. It indicates on page two of your expert report that you served as an advisor to the National Cancer Institute from 1968 to the late 1970s?

A. That's correct.

Q. Was that -- when you were serving in your capacity as an advisor, was that in connection with the National Cancer Institute's tobacco working group?

A. That's correct.

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Q. Would it be fair to say that you acted as an advisor to the tobacco working group from its inception to its termination?

A. Yes, I think I missed one meeting, which was the very first meeting.

Q. If you turn to page three of your expert report, the third paragraph down. Do you see where I am?

A. Yes, relating to tobacco working group.

Q. Cancer Institute's tobacco working group?

A. Yes, I do.

Q. Do you have an expert opinion in this case regarding the National Cancer Institute's tobacco working group?

MR. ALLINDER: Object to the form.

THE WITNESS: Yes, I have a general opinion of the work, yes.

BY MR. HEFTER:

Q. Do you have an expert opinion?

A. Yes.

Q. What is your expert opinion about the work conducted by the tobacco working group?

A. The quality of the work, conclusions and their conclusions of the work, and I guess significance of the work.

Q. What is your opinion regarding the quality of the

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work?

A. I think it was work of high quality, state of the art scientific investigations at the time, however, used a bioassay for tumorigenesis that has been criticized as probably not relevant to man. It is, however, the only bioassay that was available. I have opinions on their attempts to develop other bioassays and the results. These are particularly inhalation bioassays.

As I say, I have conclusions, overall conclusions of the work.

Q. What is your opinions about the animal inhalation bioassays that tobacco work -- relating to the tobacco working group?

A. That they all failed to produce all the efforts which were very high quality efforts failed to produce tumors in the lungs of animals that could be used for bioassay purposes of tumorigenic response. This was true of dogs that were attempted. It's true of rats, the two animal models that were explored.

Q. Do you know that there are scientific literature that's been published that has demonstrated that by use of animal inhalation studies that smoking does lead to tumorigenesis?

MR. ALLINDER: Object to the form.

THE WITNESS: If you are talking about the Witschi

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and A.J. mouse, I am aware of that, yes. I would question your conclusion, though.

BY MR. HEFTER:

Q. How would you question my conclusion?

A. These animals are animals that develop spontaneous tumors of the respiratory tract, I think virtually 100 percent tumors in their lifetime, which is relatively short and what we are talking about in the Witschi papers is some demonstration of perhaps more tumors at an earlier point in time in these animals, but not animals that don't get tumors versus responding to tobacco smoke.

Q. Are you aware of any other scientific literature or studies that has demonstrated that animals subjected to tobacco smoke in animal inhalation studies lead to tumorigenesis?

A. I am aware of other studies that asserted that. I am also aware that the attempts to repeat those studies with state of the art methodology could not duplicate the results.

Q. When you say state of the art technology could not duplicate the results, what are you referring to when you state state of the art technology?

A. Well, there were some experiments years ago where some investigators put animals in a chamber and blue smoke into the chamber and reported that they had produced some tumors. This was before we obtained specific pathogen-free

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animals, animals free of viruses for studies, and when these kind of studies were duplicated with animals that were free of virus, free of pathogens and that sort of thing and exposed to tobacco smoke in a manner similar to what human beings are exposed, you don't get a response of this nature.

Q. Has Lorillard ever conducted animal inhalation studies?

A. Yes.

Q. And have Lorillard scientists concluded that animals subjected to animal inhalation studies, subjected to tobacco smoke in animal inhalation studies, contract tumors as a result of that?

A. Lorillard has not conducted any studies where we had tumors at end point, did not produce any tumors in the animals I'm aware of that could be associated with exposure. One of our investigators that I mentioned earlier, Dr. Coggins has written a review and published it that relate to failure to produce tumors in rats and mice.

Q. Has Lorillard conducted any animal inhalation studies where any other end point besides tumors was the end point?

A. Yes, we always look at general pathology of the respiratory tract in the animals.

Q. What were some of those end points?

A. Generally end points were hyperplasia, metaplasia,

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some infiltration of macrophages. A recruitment of macrophages perhaps would be a better way to state it in the lower respiratory tract. We have looked at various end points, but the general pathology that you would normally look at.

Q. Mutagenesis?

A. We have studied -- yes, we have studied impact of additives or potential impact of additives on the immune response. I should say the potential impact.

Q. You say potential because -- strike that.

During the course of your, Lorillard's, animal inhalation studies, has Lorillard ever determined that animals subjected to tobacco smoke in animal inhalation studies contract hyperplasia?

A. Yes, we can see hyperplasia as a response.

Q. Metaplasia?

A. We have seen some metaplasia and also the reversal of these if you let the animals recover from the exposure.

Q. Microphages?

A. Yes, I mentioned that, macrophages.

Q. Macrophages is --

A. Numbers and macrophages increase as a result of the exposure.

Q. Who determined that tumor -- who determined that tumor formation should not be an end point for a Lorillard

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scientist to pursue in animal inhalation studies?

MR. ALLINDER: Object to the form.

THE WITNESS: Lorillard, as I say, is there is no information that you can produce a tumor in the animals, in terms of life long studies. We believe it's unproductive to try to do that. There have been many investigators that have tried and failed, so we use 90 day exposures, which is kind of the typical toxicological time period.

BY MR. HEFTER:

Q. Would you consider 90 day exposures to be a long term exposure?

MR. ALLINDER: Were you finished answering the last question?

THE WITNESS: Yes.

BY MR. HEFTER:

Q. I apologize if I cut you off prematurely. Do you believe that 90 day exposures is a long term experiment?

MR. ALLINDER: Object to the form.

THE WITNESS: I would consider it long term, certainly not life long experiments.

BY MR. HEFTER:

Q. Has Lorillard ever conducted life long experiments on animal inhalation studies?

MR. ALLINDER: With smoke?

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BY MR. HEFTER:

Q. With smoke.

A. Only through our sponsorship of CTR.

Q. Was Lorillard conducting animal inhalation studies from 1968 to the late 1970s when the tobacco working group was in existence?

MR. ALLINDER: Go ahead.

THE WITNESS: Lorillard was conducting some inhalation studies of a short term nature in that period. Lorillard was trying to develop methodology and techniques to conduct longer term inhalation studies.

BY MR. HEFTER:

Q. Did you ever have any conversations with any member of the North Carolina delegation to Congress regarding the workings of the tobacco working group?

A. Yes, I had a conversation with L. Richardson Preyer.

Q. L. Richardson Preyer?

A. Preyer.

Q. He is a Congressman for North Carolina?

A. He was at the time.

MR. ALLINDER: When you are asking about during the period of its existence?

BY MR. HEFTER:

Q. Correct. And my question was regarding the tobacco

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working group, were your discussions about the workings of that group?

A. No, they were around an experiment that the tobacco working group had undertaken or I should say NCI had undertaken. The tobacco working group itself was advisory.

Q. Why did you have occasion to speak to a Congressman regarding an experiment that the National Cancer Institute was performing?

A. Because the Cancer Institute was shutting down the program and getting ready to terminate one of the long term inhalation studies, and I spoke to the Congressman to try to get his support for funds to continue that direction to the NCI, to continue the inhalation experiment.

Q. Did you have any other conversations with any member of Congress from 1968 to the late '70s regarding the tobacco working group?

A. Not that I recall.

Q. Do you know that -- strike that.

Do you know that the management of the tobacco working group received warnings from members of Congress regarding the exact nature of their research and the appropriations that the tobacco working group and National Cancer Institute would receive if those findings were adverse to tobacco company interests?

MR. ALLINDER: Object to the form.

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THE WITNESS: I have never heard that.

BY MR. HEFTER:

Q. You don't know one way or the other?

A. I have never heard it.

Q. Do you know one way or the other whether members of the Carter administration, that's President Carter, exerted pressure on the National Cancer Institute to support the tobacco working group or the National Cancer Institute regarding the research it was doing on the tobacco and health?

MR. ALLINDER: Object to the form.

THE WITNESS: I don't know the time period, whether it was Carter or not, but at the end or shortly before the end of the tobacco working group, there was a change in administration within the Cancer Institute, and I believe that corresponded with a change in philosophy of the Cancer Institute given as a reason for terminating the activities and that was the National Cancer Institute should not be working on a safer cigarette as it was described and they should adopt the position that people should not smoke.

BY MR. HEFTER:

Q. Wasn't it the position of Dr. Gori that it was possible to develop a safer cigarette?

A. He thought he was making progress, yes.

Q. Wasn't it the position of Dr. Gori that smoking in

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moderation is not as bad for your health as smoking not in moderation?

A. He has published an article in that regard.

Q. Do you know where that article is published?

A. It's in the scientific literature. I don't know the journal.

Q. Wasn't it true at the time that tobacco companies agreed with Dr. Gori that smoking in moderation was not as bad for an individual's health?

MR. ALLINDER: Object to the form.

THE WITNESS: I don't believe that statement was made by tobacco companies or at least certainly not Lorillard in my recollection to the public.

BY MR. HEFTER:

Q. Did Lorillard ever take the position in the public that Dr. Gori's position on that had no scientific basis?

MR. ALLINDER: Object to the form.

THE WITNESS: I don't think Lorillard took a position to the public one way or the other.

BY MR. HEFTER:

Q. Did you ever have any discussions that other advisors to the tobacco working group from other tobacco manufacturers about Dr. Gori's position that smoking in moderation is acceptable?

MR. ALLINDER: Object to the form.

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THE WITNESS: Did I have other discussions? I don't recall any outside of the tobacco working group.

BY MR. HEFTER:

Q. Isn't it true that the tobacco companies did not share its internal research regarding chemical compounds in smoke with the tobacco working group?

MR. ALLINDER: Object to the form.

THE WITNESS: I'm not sure I understand your question. A lot of information was shared.

MR. ALLINDER: Whenever you find a convenient place to take lunch.

MR. HEFTER: That's fine.

Is it true that the tobacco companies did not share and provide to the tobacco working group the results of its skin painting experiments into the carcinogenicity of particulates in tobacco smoke?

MR. ALLINDER: Object to the form.

THE WITNESS: I don't know that I can say what other people did or didn't share. I can speak for Lorillard.

BY MR. HEFTER:

Q. Thank you. I'm only asking for Lorillard in that regard.

MR. ALLINDER: Excuse me. Would you like to restate your question or do you want me to just object to it?

BY MR. HEFTER:

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Q. Isn't it true that Lorillard did not share the results of its animal skin painting experiments with the tobacco working group?

MR. ALLINDER: Object to the form.

THE WITNESS: No, it's not true. Lorillard shared all of the information we had that was relevant to the work that the tobacco working group was doing.

BY MR. HEFTER:

Q. I take it from your answer that there was skin painting experiments that were not shared with the tobacco working group?

MR. ALLINDER: Object to the form.

BY MR. HEFTER:

Q. That you believe were irrelevant to the tobacco working group?

A. There was skin painting on fractions of the tobacco smoke condensate that Lorillard had conducted through an outside laboratory and fractionation of tobacco smoke was not of interest to the tobacco working group. That information was not shared. Information that related to the skin painting of whole smoke, much of what we participated in was published by Dr. Wynder and his associates, and therefore, was available to the tobacco working group through the open publications. So there was nothing other than this fractionation work that we did not share, and it wasn't

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relevant.

MR. HEFTER: I am going to want to read that during the lunch break, so why don't we take a lunch break now.

(Lunch recess was taken from 12:53 p.m. to 1:46 p.m.)

BY MR. HEFTER:

Q. Dr. Spears, I know you received your Ph.D. from the State University of New York in Buffalo. Are you originally from New York?

A. No, I am from Pennsylvania.

Q. Have you reviewed the complaint in the BlueCross And BlueShield of New Jersey case?

A. I have reviewed the complaint, yes.

Q. In the BlueCross And BlueShield of New Jersey case?

A. Yes.

Q. Have you reviewed any of the plaintiffs' expert reports?

A. No.

MR. HEFTER: If I could, just for clarity of the record, if I could have the answer read back from just prior to the lunch break, and the question.

(The record was read.)

BY MR. HEFTER:

Q. Had Lorillard conducted experiments into whole tobacco smoke during this period of time that were not published by Dr. Wynder?

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MR. ALLINDER: You are still talking about mouse skin painting studies?

MR. HEFTER: Yes.

THE WITNESS: I don't believe the fractionation was published. Much of it was duplicative of what was in the literature.

BY MR. HEFTER:

Q. Just so I understand your testimony correctly, correct me if I'm wrong, your testimony is that other than the fractionation work that was being conducted by Lorillard, all other animal skin painting experiments and research were conducted by Lorillard during this time period, were published by Dr. Wynder in or around this time period?

A. I believe that's correct.

Q. In 1968, isn't it correct that the tobacco working group as it became to be known was known the less hazardous -- less hazardous cigarette working group?

A. The initial name was less hazardous cigarette task force, I believe, under the lung cancer task force.

Q. Isn't it correct that tobacco companies forced the National Cancer Institute to change the name to the tobacco working group because of the implications of using the term less hazardous cigarette?

MR. ALLINDER: Objection.

THE WITNESS: I'm not aware of why it was changed.

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It came out from under the lung cancer task force.

BY MR. HEFTER:

Q. But you are not aware of why the name was changed from the less hazardous cigarette task force to the tobacco working group?

A. As I say, when it came out from under the lung cancer task force, I think the name was changed and I don't know why that name was picked.

Q. You had indicated earlier, I believe, that you could only speak to what Lorillard had provided to the tobacco working group in terms of its internal research, is that correct?

MR. ALLINDER: Object to the form.

THE WITNESS: No, I don't think that's what I said. I said I did not know what others may not have shared with the tobacco working group. I do have some appreciation of what they did share.

BY MR. HEFTER:

Q. Do you have an expert opinion regarding what information other tobacco companies shared with the tobacco working group?

MR. ALLINDER: Object to the form.

THE WITNESS: I'm not sure I would have an opinion. I may -- I have knowledge of certain things, but other things may have been shared with Dr. Gori that I would not have

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known about.

BY MR. HEFTER:

Q. The Converse is also true that you would not know information that was not shared by other companies with Dr. Gori or any other member of the tobacco working group?

A. I believe I so stated that.

Q. You testified earlier that your opinion is that the research that was conducted by the tobacco working group was significant and of high quality, is that correct?

A. That's correct.

Q. Do you have any other opinion regarding the work that was conducted by the tobacco working group?

A. I have an opinion regarding the animal inhalation work in terms of the attempts to develop a bioassay, in terms of the quality of that work, the results of that work. I have opinions on the data that was collected on cigarette variances first studied by the group and this was much of the approach was to create variations in the tobacco product and then determining whether or not there was a change in the response on mouse skin.

Q. Any other opinions regarding the work that was conducted by the tobacco working group?

A. That's the only in terms of the final conclusions, which it didn't seem practical to -- from anything that had been done to advance the commercial products beyond that

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which had already taken place. That is to say the directions that came out of the tobacco working group were consistent with directions that had already been taken by Lorillard.

Q. What were those recommendations?

A. They relate to use of reconstituted sheet and the fact that it produced a lesser response on mouse skin, that is, condensate from that, related to the use of expanded tobacco, which also produced a lesser response on skin of the animals.

Q. How had Lorillard already implemented those recommendations?

A. They were incorporated into our products. The reconstituted sheet technology was incorporated into our products in the early 1960s and the expanded tobacco was incorporated in our products in the early 1970s, maybe '71 or '72.

Q. Did there come a time when Dr. Gori became a paid consultant for the tobacco companies after the tobacco working group ceased to be in existence?

MR. ALLINDER: Object to the form.

THE WITNESS: Not to Lorillard. I believe he did have some relationship with one other company, but I don't know the details of it.

BY MR. HEFTER:

Q. Do you know which company he may have had that

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relationship with?

A. I think it was with Brown & Williamson.

Q. In forming your opinions about the quality of the work and significance of the work that was conducted by the tobacco working group, do you rely on any documents in forming the basis for your conclusions?

MR. ALLINDER: Object to the form.

THE WITNESS: I rely on all the publications of the -- that came out of the tobacco working group. I rely on the opinions of the advisory group which were I think the foremost experts in the world with respect to the subjects that the tobacco working group was investigating, as well as individuals who came and entered into discussions about specific subjects from time to time with the tobacco working group. There were other scientists.

MR. HEFTER: Can I have that read back.

(The record was read.)

BY MR. HEFTER:

Q. Do you rely on any internal documents of the tobacco working group in forming your opinions regarding the tobacco working group?

MR. ALLINDER: Object to the form.

THE WITNESS: There were internal documents that led to the publications and, yes, they would be part of it.

BY MR. HEFTER:

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Q. The opinions of the advisory group that you referred to, when you refer to them, are you referring specifically to written opinions of the advisory group?

A. No, verbal opinions.

Q. And these would be verbal opinions that these individuals provided at meetings of the tobacco working group?

A. That's correct.

Q. Are you relying on any verbal opinions that were conveyed to you outside of the context of tobacco working group meetings?

MR. ALLINDER: Object to the form.

THE WITNESS: I don't believe so.

BY MR. HEFTER:

Q. Isn't it true that Dr. Gori's statement that smoking in moderation is acceptable in his publication, isn't it true that that statement benefited the tobacco companies?

MR. ALLINDER: Object to the form.

THE WITNESS: I don't believe so. Certainly Lorillard's sales didn't change as a result of that statement that I'm aware of.

BY MR. HEFTER:

Q. Do you know what year Dr. Gori made that statement?

A. I believe it was toward the end of the tobacco working group, but I can't give you a year, probably in the

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late '70s.

Q. From 1975 to 1985, did the sales of Lorillard Tobacco products increase or decrease?

A. '75 to '85, I think they were increasing in that period.

Q. Would it be fair to say that the whole purpose of the tobacco companies involvement in the tobacco working group was to get the federal government to endorse the concept of a less hazardous cigarette in order to make sure that people continued to smoke?

MR. ALLINDER: Object to the form.

THE WITNESS: No, I would not characterize it in that fashion.

BY MR. HEFTER:

Q. How would you characterize it?

A. I would say that it was an effort that was initiated by the Cancer Institute, a Dr. Baker at the time and Dr. Endicott who was I think then -- I think Baker was the director of the Cancer Institute at the time and Endicott was at some higher level, and the two of them initiated the activity under, as I said, the lung cancer task force and they had obviously a major effort directed to lung cancer and they felt it was important, I guess, to start an activity that relates to tobacco smoking and try to determine whether you can produce a safer product.

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Q. Do you recall having any discussions at the time about the notion of boycotting the tobacco working group, tobacco companies boycotting participation in the tobacco working group?

MR. ALLINDER: Object to the form.

THE WITNESS: I had no such conversation.

BY MR. HEFTER:

Q. Do you know if any member of management of Lorillard had any discussions regarding boycotting participating in the tobacco working group?

MR. ALLINDER: Object to the form.

THE WITNESS: I'm not aware of any such discussions, but it might help if you tell me who you think at Lorillard and with whom might have had such a conversation.

BY MR. HEFTER:

Q. I'm not -- my question was not whether you had any questions. I think you answered that whether you had any discussion. I think you answered that previously. My question is, do you know of any other discussions within Lorillard between other members of management relating to whether Lorillard would or would not boycott participating in the tobacco working group?

MR. ALLINDER: Object to the form.

THE WITNESS: I don't know about the word boycott

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but there were discussions as to whether I would participate in the tobacco working group before I sent a letter accepting the invitation.

BY MR. HEFTER:

Q. The discussions that we are referring to, would it be fair to say that -- strike that.

The discussions that you are referring to, were those discussions relating to whether you should be the person to represent the company on the tobacco working group or whether the company should have a representative at the tobacco working group meetings at all, if you recall?

A. My discussions were with the person to whom I reported at the time, and it was specifically whether I would participate and the invitation came directly to me.

Q. Did the individual who you are referring to, what is that person's name?

A. Edgar Bennett.

Q. Did Mr. Bennett express any reservations to you about the participation of a Lorillard representative at the working group?

A. No, he did not.

Q. Do you know if Mr. Bennett had any discussions with -- what position was Mr. Bennett in?

A. President -- I believe he was president at the time.

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Q. Do you know if Mr. Bennett had discussions with any other member of management about reservations he or anybody else had about your participation on the tobacco working group?

A. I do not know, but he did not discuss any reservations by others with me.

Q. Would it be fair to say that you would not know whether members of management at the other tobacco companies expressed reservations about participating on the tobacco working group?

A. I would not know.

Q. Did any member of any other tobacco company -- strike that.

Did any employee or officer of any other tobacco company express reservations to you about tobacco company manufacturers being represented on the tobacco working group?

A. No.

Q. Isn't it correct that the purpose of tobacco companies in participating with the tobacco working group was to prevent the tobacco working group from coming up with adverse biological findings regarding cigarette smoke?

MR. ALLINDER: Object to the form.

THE WITNESS: No, that was not the purpose at all.

BY MR. HEFTER:

Q. Have you been privy to any internal communications

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between employees of other tobacco companies about whether the purpose of their participation on the tobacco working group was to prevent adverse biological findings by that body?

MR. ALLINDER: Object to the form.

THE WITNESS: No, I'm not privy to any such conversation.

BY MR. HEFTER:

Q. So if one of Philip Morris' purposes in sending a representative to the tobacco working group was to prevent that body from coming up with adverse biological findings regarding cigarette smoke, you would not know one way or the other?

MR. ALLINDER: Object to the form.

THE WITNESS: I would not know if that was some internal communication within Philip Morris, no, I would not know.

BY MR. HEFTER:

Q. The same thing would be true for any other U.S. manufacturer who had a representative on the tobacco working group other than Lorillard?

A. Unless they publicly stated it, I would not know.

Q. Do you know who a Dr. Homberg was?

A. Yes.

Q. Can you tell me who Dr. Homberg was?

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A. He was an M.D., I believe, that ran an organization called Bio-Research Consultants out of the Boston area.

Q. Did Lorillard contract with Bio-Research Consultants to perform biological testing of tobacco smoke?

A. Yes, they did.

Q. Can you describe for me what biological testing Bio-Research conducted for Lorillard Tobacco Company?

A. They conducted experiments on skin painting that related to the fractionation of cigarette smoke condensate that I mentioned earlier. They conducted some experiments relating to ciliastasis. I believe they may have done some analyses with respect to radioactivity presence in tobacco or tobacco smoke. I don't recall any others at the moment.

Q. Do you recall when Bio-Research Consultants performed this work for Lorillard?

A. In the early mid 1960s -- I would say mid 1960s.

Q. Would it be fair to say that Dr. Homberg was the research director of Bio-Research Consultants?

A. He was the principal. I'm not sure what his title was.

MR. ALLINDER: Michael, for the record, I think it's Homberger.

MR. HEFTER: Thank you.

Did Dr. Homberger publish the results of his research that was conducted on behalf of Lorillard Tobacco

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Company.

THE WITNESS: I think he published some of it, but -- yes, I believe he published some of it. The fractionation work was not published, and it was basically to try to duplicate what had been published by Dr. Wynder's laboratory, and most of it did duplicate that work.

BY MR. HEFTER:

Q. You indicated that the fractionation work was not published, is that correct?

MR. ALLINDER: Object to the form.

THE WITNESS: It had already been published by Dr. Wynder and since this was more or less duplicative, it would not be published.

BY MR. HEFTER:

Q. Was his work on ciliastasis published?

A. I believe it was.

Q. Was his work on the radioactive to be present in tobacco smoke published?

A. I don't think so. This was a small experiment which in itself was not have yielded a publishable document.

Q. Did Lorillard have the right to -- strike that.

Did Dr. Homberger require Lorillard's prior consent before publishing any of his work?

MR. ALLINDER: Object to the form.

THE WITNESS: I would have to go look at the

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contract, but normally a contract would say Lorillard would be the owner of the work, and therefore, would have control over its publication.

MR. HEFTER: Let's mark this as the next exhibit.

(Exhibit No. 5 marked for identification.)

BY MR. HEFTER:

Q. And for the record, I just marked as Spears Exhibit No. 5 the decision of the United States Supreme Court, Food And Drug Administration versus Brown & Williamson Tobacco Corp, et al., decided March 21, the year 2000.

Have you read a copy of the Supreme Court's decision in the FDA case?

A. I have scanned it. I haven't read the whole thing.

Q. It was provided to you?

A. Yes.

Q. When was it provided to you?

A. It was provided to me by the research library probably the day after it appeared.

Q. I'm going to turn your attention to page one of the opinion of the court. It's page five of the exhibit. The first sentence of the opinion written by Justice O'Connor reads this case involves one of the most troubling public health problems facing our nation today: The thousands of premature deaths that occur each year because of tobacco use.

Do you agree with the United States Supreme Court

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that thousands -- there are thousands of premature deaths in the United States that occur each year because of tobacco use?

MR. ALLINDER: Object to the form.

THE WITNESS: I disagree in the sense that I think this is a mathematical calculation. It involves trying to apportion the number of cases of various diseases along the risk factor numbers that have been produced in various epidemiological studies, and I don't believe this is a valid mathematical technique for such a calculation.

BY MR. HEFTER:

Q. How do you know what mathematical technique the court went through to determine this statement?

MR. ALLINDER: Object to the form.

THE WITNESS: I don't think the court went through any technique. I think they picked this number out of the number that the Center for Disease Control has published and it's been referred to in many documents. It's the same general number in terms of number of deaths claimed. So I'm assuming that's where it came from and that's the opinion I have regarding it.

BY MR. HEFTER:

Q. Do you believe there is any premature death in the United States as a result of tobacco use?

MR. ALLINDER: Object to the form.

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THE WITNESS: I don't know, unless you are willing to assume that the epidemiological studies are reflective of those premature deaths in terms of -- and smoking being the cause.

BY MR. HEFTER:

Q. Do you agree with the epidemiological studies that smoking is the cause of premature deaths in the United States?

A. Well, the epidemiological studies produce what are known as risk factors, statistical associations between disease and possible causes. They in themselves do not prove cause in the general sense, although I think the public health service and the public health authorities have adopted that as causative if you have consistency among these studies, and Lorillard does not disagree with the position they have taken.

This kind of data is reflective of causative, particularly if you are interested and concerned about the conservative approach to public health.

Q. Do you believe that smokers have a greater risk of contracting lung cancer than non-smokers?

A. Smokers as a group are indicated to have greater risk than non-smokers as a group.

Q. Do you have a personal opinion as to what the greater relative risk that a smoker has than a non-smoker has

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for getting lung cancer?

MR. ALLINDER: Objection to the form.

THE WITNESS: It varies in terms of the risk factor. The magnitude of the risk factor varies with the various epidemiological studies and it also varies in most of the studies with the number of cigarettes smoked. So there is not a single number. It depends on these particular variables, which study are we talking about and what is the level of smoking we are talking about in terms of number of cigarettes.

BY MR. HEFTER:

Q. Do you believe that under any dose response relationship that a smoker has a greater relative risk of contracting lung cancer than a non-smoker?

A. Yes, I already said that, as a group they have a greater risk.

Q. Has Lorillard ever publicly stated that smokers have a greater relative risk of contracting lung cancer than non-smokers?

MR. ALLINDER: Object to the form.

THE WITNESS: I have certainly stated it in my depositions that I have given over time. I have not had a press release for something like that if that's what you mean.

BY MR. HEFTER:

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Q. Other than in your depositions, has Lorillard taken or has Lorillard stated publicly that smokers have a greater relative risk for contracting lung cancer than non-smokers?

MR. ALLINDER: Object to the form.

THE WITNESS: I don't believe so.

BY MR. HEFTER:

Q. Do you believe that smokers have a greater relative risk for contracting any other disease than non-smokers?

MR. ALLINDER: Object to the form.

BY MR. HEFTER:

Q. Other than lung cancer?

MR. ALLINDER: Same objection.

THE WITNESS: Yes. There are other studies that involve cardiovascular disease where the relative risk is increased, not of the magnitude that you find with the lung cancer relative risks. The same is true I think for emphysema. The same is true for I guess chronic bronchitis, and there have been other studies which make other assertions, but many of these I don't think have been confirmed to the degree that it has in the diseases I just mentioned.

BY MR. HEFTER:

Q. Would you agree from an epidemiological point of view that smoking causes lung cancer?

MR. ALLINDER: Object to the form.

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THE WITNESS: From an epidemiological point of view I think smoking is a risk factor and that in my judgment is all one should conclude from an epidemiologic study or studies. I think if you -- as I said before, if you are in the public health service or protecting the health of the public, you could reasonably take this as causative and we have not -- Lorillard does not disagree with that interpretation.

BY MR. HEFTER:

Q. Has Lorillard conducted toxicological studies to determine whether any compound in tobacco smoke is carcinogenic?

A. Carcinogenic to animals, yes. We have had a program and continue a program of testing any additives that we employ to tobacco to determine whether or not they in the smoke media produce any change in response in animals. This is both with respect to mouse skin and with respect to the inhalation assay that I mentioned earlier, and also a number of in vitro assays.

Q. You refer to in vitro assays. Can you describe for the record what an in vitro assay is?

A. Generally in vitro is something that's done outside of the whole animal. It uses animal parts or cells not necessarily just animal parts, but living components and/or cells and carry out tests at that level without the intact

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organism.

Q. Has Lorillard Tobacco Company ever conducted in vitro assays of human cells to determine the carcinogenic nature of any compound or part particulate in tobacco smoke?

A. No. Most of the human cells are in tissue cultures and I think it's been our general opinion that these are not very producable, and there is not a standard test using tissue culture. I can't fully remember whether we experimented with HeLa cells, which are a human cell lung. I just don't remember. It's possible.

Q. Based on -- strike that.

When was the first time that Lorillard Tobacco Company conducted skin painting experiments?

A. In the 1960s.

Q. Were you part of the research -- strike that.

Let me finish. Were you one of the researchers who conducted skin painting experiments for Lorillard Tobacco?

A. I conducted a part of the experiments in terms of the fractionation work that we did that was done either by me or my direct supervision. I participated in the planning of the skin painting studies. They were done as I pointed out at Dr. Homberger's laboratory, and also Dr. Wynder's laboratory where we were providing materials to that laboratory as well.

Q. So would it be fair to say that Lorillard did not

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conduct in-house its own skin painting experiments in the 1960s?

A. We did not house animals for that purpose.

Q. Did Lorillard contract with any other outside entity other than Dr. Homberger's and Wynder's laboratories in the 1960s for conduction of skin painting tests?

A. There was -- I can't give you the exact time. It may have been before the 1960s, but there was some work at I think Johnson & Johnson, and this was an attempt to replicate Dr. Wynder's earliest skin painting result.

Q. Why did the company need to replicate Dr. Wynder's results if his results were already published?

MR. ALLINDER: Object to the form.

THE WITNESS: There had been many published results that could not be replicated, and I think if something is published then the first thing you want to do is see if you can replicate it, if not, fine.

BY MR. HEFTER:

Q. Wasn't the purpose of the skin painting experiments that were contracted for by Lorillard to dispute the validity of Dr. Wynder's results?

MR. ALLINDER: Object to the form.

THE WITNESS: Not at all.

BY MR. HEFTER:

Q. Other than Dr. Homberger's, Dr. Wynder's and

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perhaps Johnson & Johnson, do you recall any other skin painting experiments that were contracted for by Lorillard during the 1960s?

A. No, I do not.

Q. Does Lorillard continue to conduct skin painting experiments today?

A. We do conduct them today.

Q. Do you conduct them in-house today?

A. No, they are conducted at consulting laboratories.

Q. Has Lorillard ever conducted skin painting experiments in-house?

A. No, we have not.

Q. Isn't it correct that the purpose of the skin painting experiments at Lorillard has never been to determine the carcinogenic nature of any compound in tobacco smoke?

MR. ALLINDER: Object to the form.

THE WITNESS: That's not correct.

BY MR. HEFTER:

Q. Can you identify any research skin painting experiment that was contracted for by Lorillard whose purpose was to determine whether or not a part particular compound or particulate in tobacco smoke was carcinogenic?

MR. ALLINDER: Object to the form.

THE WITNESS: To mouse skin and that was the purpose of the work that went on at the Homberger

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laboratories as well as Wynder laboratories.

BY MR. HEFTER:

Q. And those are the only research experiments of the skin painting nature that was conducted by Lorillard for the purposes of determining whether or not a compound or a particulate in tobacco smoke is or is not carcinogenic?

MR. ALLINDER: Object to the form.

THE WITNESS: No. Those experiments like that go on today at other laboratories, and the purpose of those is to determine whether or not additives that we might employ on tobacco appear in the smoke and influence the tumorigenic response on mouse skin.

So the mouse skin assay continues to be used because it is the only assay that produces a tumorigenic response. It's not used because we think it's a totally relevant assay, but it is the only one that scientists have to use in this field.

Q. Has Lorillard Tobacco's research experiments concluded based on the skin painting experiments that have gone on from the '60s to the present, have they determined that any additive that's used by Lorillard in its tobacco products are tumorigenic?

MR. ALLINDER: Object to the form.

THE WITNESS: The answer to the question is difficult because that is not the only thing that we rely on

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to make the determination. There are mutagenic tests we conduct and if potential additive fails in mutagenic tests, then it doesn't go on to the skin painting and the more expensive long term studies.

So there is a protocol here that carries through a series of tests from short term least expensive to the most expensive, which are the long term skin painting inhalation studies. So that we would reject items that appear early on to be suspicious by virtue of mutagenic.

If we see something mutagenic, we would not carry that forward in any additional testing. We say we would not consider this further. It's unlikely you would get in the end product skin painting a major difference or significant difference with respect to an individual compound. I don't believe we have, but I would have to look back at all the data and make sure that's correct.

BY MR. HEFTER:

Q. Have there been additives that Lorillard has researched that have passed the mutagenic tests but have been included in the product because they have not failed the tumorigenic test?

A. No.

Q. So if a product fails the tumorigenic test --

A. Automatically would be out.

Q. I recall you testifying earlier that you did not

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conduct tumorigenic tests past 90 days, is that correct?

A. That's the inhalation. That does not produce tumors.

Q. So the tumorigenic test that you conduct --

A. Is mouse skin.

Q. Is mouse skin painting, correct -- I apologize, you are the one who is testifying.

The tumorigenic mouse skin painting studies that you conduct, how long do those generally take?

A. It is varied over time in that we change the strain of animals over time and we have a strain that gives a response to our controls in about I think between six and 12 months. Prior to that we would run 15 to 18 months.

Q. The tumorigenic and mutagenic test that you run are experiments into the mutagenic or tumorigenic properties of additives, is that correct?

MR. ALLINDER: Object to the form.

THE WITNESS: That's correct.

BY MR. HEFTER:

Q. Has Lorillard Tobacco Company ever conducted animal skin painting tests to determine whether any part particulate in whole smoke is or is not carcinogenic?

MR. ALLINDER: Object to the form.

THE WITNESS: Smoke condensate as we collect it is tumorigenic in mouse skin painting and it was shown back in

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the 1960s, and we have used that assay with variations including more sensitive animals, what have you, over time. So, yes, cigarette smoke condensate selected and applied in sufficient quantities to the backs of susceptible mice give you a response.

BY MR. HEFTER:

Q. My question is, is with respect to any particular compound in cigarette smoke, has Lorillard Tobacco Company isolated that compound and conducted a study to determine whether a particular compound in the tobacco smoke is tumorigenic?

MR. ALLINDER: Object to the form.

THE WITNESS: Benzo(A)pyrene is frequently used and may be used as a control in many of these studies. It's applied at a level that gives a positive response and benzo(A)pyrene is a component of tobacco smoke. We have isolated it and identified it in tobacco smoke and there is no question if you apply it in sufficient quantities to the skin of the animal, you will get a tumorigenic response, but just so you are not led, it's many, many times the concentration that's found in tobacco smoke that gives that response.

BY MR. HEFTER:

Q. Do you believe that benzo(A)pyrene, BAP for short, is that correct?

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A. Correct.

Q. Is a human carcinogen?

A. I think in terms of the IR classification I believe it's an animal carcinogen and it's a suspect human carcinogen, but I'm not 100 percent positive.

Q. Other than the mouse skin paintings, has Lorillard Tobacco Company ever conducted any other toxicological study to determine whether benzo(A)pyrene is a human carcinogen?

MR. ALLINDER: Object to the form.

THE WITNESS: There isn't any other study unless you had groups exposed to benzo(A)pyrene, humans exposed to benzo(A)pyrene in some sort of a workplace or environmental setting. That's why I think it's a suspect rather than a proven human carcinogen. That data does not exist. There is data from long ago that roofers have a higher incidence of some contact cancer and roofing materials at the time contained more benzo(A)pyrene.

The same thing is true with chimney sweeps and there is inferences that this may be benzo(A)pyrene, but it can't really be proven directly. There is more in the chimney sweep -- in the chimney materials than just benzo(A)pyrene.

MR. HEFTER: How long have we been going, Bill? Let's take a break.

(Recess was taken from 2:44 p.m. to 2:53 p.m.)

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BY MR. HEFTER:

Q. As a result of Lorillard's skin painting experiments has Lorillard determined that any compound other than benzo(A)pyrene in tobacco smoke is tumorigenic?

MR. ALLINDER: Object to the form.

THE WITNESS: To mouse skin?

BY MR. HEFTER:

Q. To mouse skin.

A. Yes, we have used -- I believe we have used dibenzanthracene and maybe benzanthracene as controls from time to time. They are also components of tobacco smoke, again in very trace quantities. We have conducted experiments where we have added phenols and some of the fatty acids which were suspect carcinogens by at least some people and catechol, which is another compound in tobacco smoke that's thought to be a carcinogen.

We have participated in formulating experiments that relate to those materials.

Q. During the course of these experiments, has Lorillard Tobacco Company determined that any one of the compounds or acids that you just identified are animal carcinogens?

MR. ALLINDER: Object to the form.

THE WITNESS: They are not carcinogens. The question is whether or not they influence the response you

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get on mouse skin when you put tobacco smoke condensate on the mouse skin, which contains these materials and our best answer was that if they have an influence it's slight, and we have never been able to explain the response on mouse skin in terms of individual compounds that are present in cigarette smoke condensate.

To the best of my knowledge, that is not untrue of Lorillard, but true of all of the investigators that work in this field. There is no chemical definition of cause of cigarette smoke condensate on mouse skin.

Q. I'm talking about not only mouse skin now. What I'm talking about is any other toxicological testing that Lorillard has done or contracted for. Has Lorillard made the determination that any compound in tobacco smoke is carcinogenic to animals?

MR. ALLINDER: Object to the form.

THE WITNESS: I don't believe so. The only other experiments relate to nitrosamines and we have not specifically conducted nitrosamine experiments that I can recall.

BY MR. HEFTER:

Q. And that would be true in-house or by contract?

A. Yes.

Q. Are nitrosamines a known animal carcinogen?

A. Some of the nitrosamines are, not to mouse skin.

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Q. Would it be fair to say that it is your opinion that it is impossible in any toxicological study to determine whether any chemical compound is a human carcinogen?

MR. ALLINDER: Object to the form.

THE WITNESS: By virtue of an animal experiment the answer is yes.

BY MR. HEFTER:

Q. By virtue of any toxicological study, human or animal, would your answer be the same?

A. No. If there has been a human exposure to the agent you can determine whether or not you have a tumorigenic response and in the humans that were so exposed. This is a case with say uranium miners, you have the exposure to the radiation and determination can be made that radiation is carcinogenic in humans. If the only thing you add was animal data you couldn't reach that.

Q. Let's take the uranium miners example that you put forward. How would a toxicologist determine whether radiation exposure is carcinogenic in the context of an exposed population? What tests would they perform?

A. Carry out epidemiologic studies. In other words if the relative incidence of tumors, may be a specific tumor type among uranium miners is the incidence different than it is in a population that's not exposed.

It's a classic epidemiologic study and you would

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couple that with animal experiments to confirm again the direct response because there could be confounders present in the epidemiological study that you couldn't account for, were not accounting for. So you need the animal conformational information and it's also nice to have information at a cellular level that the radiation is indeed changing the cellular mechanisms.

Q. How would you determine whether at the cellular level the exposure was changing the cellular mechanisms?

A. Whether or not you were seeing changes in the nucleus, chromosome breakage, lesions. You could also look at adduct formation in today's kind of state of the art.

Q. And one would determine whether there is breakage, deletion or adduct formation by looking at those individuals tissues, is that correct?

A. Yes, that's correct.

Q. Has Lorillard Tobacco Company ever looked at the tissues of smokers to determine whether there is breakage, deletion or adduct formation?

MR. ALLINDER: Object to the form.

THE WITNESS: I'm sorry, I was speaking of animals when I said you would do that work as conformational work to the epidemiological observation of a higher risk among uranium miners.

BY MR. HEFTER:

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Q. Is it possible to look at human tissue to determine breakage, deletion and adduct formation?

A. It may be.

Q. Has Lorillard Tobacco ever looked at human tissue to determine breakage, deletion or adduct formation as a result of tobacco smoking?

MR. ALLINDER: Same objection.

THE WITNESS: No, Lorillard has not. I am trying to recall. I don't think there is any demonstration of that among tobacco smokers.

BY MR. HEFTER:

Q. What is the basis for you saying that?

A. I'm trying to recall the literature.

Q. Do you know of any literature which has determined that there is adduct formation based on tobacco use?

A. There is literature that would suggest that there is adduct formation. There is general adduct formation with aging, and I would say my interpretation of the literature is that the same adducts are present in smokers as there are in aging non-smokers.

Q. What is the basis for your statement?

MR. ALLINDER: Were you done with your answer, Dr. Spears?

THE WITNESS: Yes, I said that's my --

BY MR. HEFTER:

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Q. What is the basis for your last statement?

A. That is my summary of the literature that I have reviewed on this material.

Q. Have you put together a list of the literature that you have reviewed?

A. I don't have a specific list on that subject.

Q. Does it form the literature that you reviewed with respect to this subject form the basis of any opinion that you purport to express in Spears Exhibit No. 1?

A. I don't think so. Let me make sure. It doesn't unless I am asked a question in this regard.

MR. HEFTER: Let me just state for the record just because I think I need to make a statement for the record that to the extent that -- you know our position about whether, in fact, this document, Exhibit No. 1, actually states any expert opinions, but to the extent that Dr. Spears intends to offer expert opinions, we are entitled to a list of his reliance documents, the documents which form the basis for his opinion and those of which he is relying which we do not have as part of this report or otherwise.

MR. ALLINDER: I understand your position and I will take it under advisement. So far as I know, the list of reliance materials that is appended to and is part of Exhibit No. 1 is complete. I will certainly confer with Dr. Spears and should there be any supplementation required we'll

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provide it promptly.

MR. HEFTER: Again, I reserve the right to review that material and re-depose Dr. Spears, if necessary.

MR. ALLINDER: I note your position.

BY MR. HEFTER:

Q. If researchers were able to determine breakage, deletion and adduct formation as a result of tobacco company, wouldn't it be true that smoking would be a cause of that individual disease?

MR. ALLINDER: Object to the form.

THE WITNESS: I don't think you can conclude that because there are repair mechanisms which are also operative and to determine whether or not you get a tumor is not known.

THE WITNESS: But it is known there are repair mechanisms which repair genetic damage that cause cell death if DNA cannot be repaired, so there are control mechanisms that are operating to prevent these mutations from becoming incorporated in the cells that become cancerous.

BY MR. HEFTER:

Q. Isn't it true there is scientific literature that's been published that smoking prevents the control mechanisms to work properly?

A. There have been a lot published in the field, but I don't believe there is -- I don't believe there is a significant number of papers that say that the adducts and

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the numbers of adducts found in smokers is very different from that found in non-smokers, and as I said before, I think many of these adducts are the same adducts that appear with age.

Animal experiments have been conducted which demonstrate that, so that obviously something is going on that prevents most people from developing tumors. So that this obviously is not the whole story, cannot be the whole story. It's a piece of scientific evidence I think at this point.

MR. HEFTER: Can I have that read back.

(The record was read.)

BY MR. HEFTER:

Q. Are there any papers that have determined that smokers have more adducts than non-smokers?

A. There have been claims, yes, and some of the methods for determining adducts have been abandoned with newer methods taking place. I think, for example, there is I believe a fluorescence procedure that was used. There is P-32 labeling which is another procedure and some of the adducts that are separated with P-32 labeling were thought to be unique, but really unresolved in chromatography procedures and solvent extraction procedures.

New procedures have been developed and what were thought to be, for example, benzo(A)pyrene adducts no longer

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look like they were benzo(A)pyrene adducts. So I stick with my conclusion that this is an emerging field. There is a lot of publications. Some of them are not repeatable. Newer techniques are showing some of the earlier interpretations were not correct.

Q. Has Lorillard Tobacco Company performed any studies using the P-32 method that you describe?

A. Not in humans, human material. We have in bacteria.

Q. What were you looking for in those studies?

A. Looking for adduct formation.

Q. In animals?

A. No, in bacteria.

Q. And were the results of your studies using the P-32 technique such that you determined there was adduct formation in bacteria as a result of tobacco smoke?

A. We have a response from bacteria that we were trying to explain by determining -- trying to determine whether or not there were adducts being formed by a response to tobacco smoke, and to my knowledge, that work has not concluded. There have been experimental difficulties in even isolated DNA from bacteria. It's not -- every organism presents some special challenges to isolating the DNA to begin with.

So you have to try to work out all these techniques

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without destroying the adducts and that's some of the complications that are involved in this type of research. I think in answer to your question, the answer is, no, we have not concluded that adducts are formed as a response to tobacco smoke, exposure in these bacteria.

Q. But you have concluded that some adduct formation has occurred in these experiments?

MR. ALLINDER: Object to the form.

THE WITNESS: You see adducts, but whether they are due to smoke or not, that's another question.

BY MR. HEFTER:

Q. It is possible they formed as a result of smoking?

MR. ALLINDER: Object to the form.

THE WITNESS: I think that's a mischaracterization of what I intended to say. I think we are saying at this point we are not able to isolate adducts from either exposed or non-exposed.

BY MR. HEFTER:

Q. You mentioned before a fluorescent chromatography?

A. Yes, I believe that's right.

Q. Is the fluorescent chromatography the same as the P-32 experiments or is that something different?

A. No, something different. We have not applied it, but it's a technique that was reported in the literature that turns out to be less sensitive than P-32 post-labeling.

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Q. I think I heard you correctly when you said that you have not -- when I say you, Lorillard, has not availed itself of the fluorescent chromatography technology?

A. That's correct.

Q. How would you describe the P-32 fluorescent chromatography? Is there an easy way to describe those types of studies?

MR. ALLINDER: Object to the form.

THE WITNESS: They are studies where you are trying to isolate adducts and you are trying to tag the molecules with something because they are there in very small concentrations, and the P-32 post-labeling technique is where you are labeling your DNA fragments, which presumably contain adductive materials with something that you can analytically determine.

One such approach is tag it with something that's fluorescent since fluorescent procedures can be highly sensitive, and another is to tag it with radioactive materials, such as P-32. So this gives you a tag when you are trying to isolate something in minute, really minute quantities.

BY MR. HEFTER:

Q. Other than the P-32 experiment, has Lorillard Tobacco Company used any other experimental technique to determine, to try to isolate adducts?

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A. Not to my knowledge, but I don't know what they would be otherwise.

Q. You don't know of any other technique in the scientific literature to determine adduct isolation other than the P-32 experiments and the fluorescent chromatography?

MR. ALLINDER: Object to form.

THE WITNESS: There is certainly other techniques if you take DNA in large quantities and put it in a test tube and subject it to something like benzo(A)pyrene or benzo(A)pyrene diol, the active form. You can certainly isolate adducts in that kind of an environment, but if you go to a living cell and expose it, then you are looking at very minute quantities and that's a new challenge.

BY MR. HEFTER:

Q. Has Lorillard Tobacco ever conducted the type of test you just described?

A. I don't believe so.

Q. When was the first time Lorillard Tobacco Company used animal inhalation studies?

A. We started some animal inhalation studies back in the early 1960s that related to work that we did on ciliastasis.

Q. Does Lorillard Tobacco Company -- and I apologize, were you finished?

A. Yes.

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Q. Does Lorillard Tobacco Company conduct animal inhalation studies today?

A. Yes.

Q. And is it fair to say that from the 1960s to the present, Lorillard Tobacco has employed animal inhalation studies continuously throughout that time period?

A. Essentially continuously. I wouldn't know -- there are probably times when there wasn't an experiment running, but as I say, essentially continuously in some animal, rather.

Q. What was the or what is the purpose of the animal inhalation studies that the company is conducting today?

A. I thought I answered that, but it's to investigate additives that we would potentially use in our products either as flavors or for some other purpose.

Q. I recall your testimony on that and just so I'm clear and the record is clear, do the animal inhalation studies that Lorillard Tobacco has conducted from the '60s to the present, have they had any purpose other than to determine -- other than to study the additives that are placed in their products?

MR. ALLINDER: Object to the form.

THE WITNESS: Yes. The initial studies were involve looking at what I call ciliastasis and we had in our own laboratory experiments as well as in a consulting

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laboratory a couple of investigators who were working with us, but there were studies that involved various animals where you could easily observe ciliary action, and some of those were the cat, the rabbit and we used clam gills and frog esophagus.

Over time these different organisms in animals were used for that purpose. Most of that was back in the 1960s in terms of start and ran into the 1970s.

BY MR. HEFTER:

Q. Other than to study ciliastasis and to study the additives, has there been any other purpose behind the animal inhalation studies?

A. Right, well, we also in the same time frame looked into the lower respiratory tract and studied the free lung cells that were there, including macrophages and their function, as for how well they functioned with respect to being able to kill bacteria.

So we were basically looking at the lung defense mechanisms and whether cigarette smoke had an impact on these mechanisms.

Q. What were your conclusions about whether cigarette smoke had an effect on those lung mechanisms?

MR. ALLINDER: Object to the form.

THE WITNESS: You could demonstrate in these kind of experiments that you could certainly expose them to high

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enough levels of tobacco smoke that you can create a response, but to interpret that I think was more a result of other investigators' work where they were looking at human individuals in terms of pathology, in terms of muco-ciliary clearance, using some short-lived radioisotope and that sort of thing, and the general conclusion is in the average smoker the ciliary activity is functioning as well as the macrophage activity.

It's interesting to note that viral infections cause kind of a stripping of the respiratory tract with respect to cilia and must regenerate.

BY MR. HEFTER:

Q. I'm sorry, I just didn't hear the last few words.

A. I said and then they regenerate when you get over the viral infection.

Q. As a result of your studies, the lower respiratory tracts, did you conclude that there was any diminishment of ciliary activity?

A. In these models you could demonstrate that. We then went further because there were attempts to determine what in tobacco smoke was causing the response and most of the response is due to the so-called vapor phase components that are water soluble.

We conducted experiments that demonstrated that many of these components that affected ciliary activity in

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the animal experiments were absorbed in the oral cavity and did not go into the lower respiratory tract.

Q. Are you aware that there is scientific literature which suggests the exact opposite, that there is significant ciliary diminishment in the lower respiratory tract as a result of tobacco smoke?

A. There are no ciliary in the lower respiratory tract. I am talking about the alveolar area of the lung.

Q. Did Lorillard Tobacco Company ever publish any of the results of its animal inhalation studies?

A. I think so. I know we certainly presented it at conferences.

Q. Do you recall -- can you recall any specific conference at which any animal inhalation study was presented?

A. If I look at my curriculum vitae, that can help. Yes, there is one publication difference in cilia toxicity of cigarette smoke, comparison of two methods, published in the American Review of Respiratory Diseases by Dalhamn, Rylander and myself.

Q. Where are you referring to, sir?

A. I am referring to page seven, top of the page.

Q. Do you know if Lorillard Tobacco Company has published the results of any animal inhalation study that it has conducted since 1967?

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A. Yes.

Q. Can you identify those for me?

A. There was a publication I think a year or so ago, and I can't remember the journal, but it is a summary of many different inhalation studies that Lorillard has conducted. It might be Food Safety or something like that may be the journal, I don't know.

Q. Do you recall any others other than --

A. Not as published. In that particular article is a tremendous amount of data. It's years of work in that one article.

Q. Other than this Food Safety article --

A. No, that is the publication covering the inhalation studies that we have done from that period that you are talking about.

Q. And the period we are talking about is from 1967 to at the time of the publication?

A. Well, these are experiments I think that were conducted largely between, say, 1980 and presently.

Q. From 1967 to 1980, do you recall Lorillard publishing any animal inhalation studies, the results of those?

A. No, that's the period of time that we were trying to develop the methodology. It's a period of time the tobacco working group was off working and we were being

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supportive of their work, and internally we were looking at methods as well, how to get deposition in the lower respiratory tract of the animals, whether you were or not. All of that kind of methodology was being done at Lorillard. So it predated the actual inhalation experiments.

Q. What is ciliastasis?

A. Cilia are cells that have a structure called a cilium, which is a protrusion, hair-like structure. These cells line the upper respiratory tract, the trachea, major bronchi and their purpose is to beat in unison in order to propel mucus up out of the respiratory tract and propel up, then any particles or materials that are on the mucus layer. So it's a mechanism of removing materials from the upper respiratory tract, sometimes called the muco-ciliary escalator.

Q. My question is what is ciliastasis?

A. If those cells stop functioning then you call it a ciliostatic event.

Q. Based on the toxicological study that have been conducted at Lorillard, does smoking cause ciliastasis?

A. We cannot say from the studies at Lorillard, but we can say that we can demonstrate in animals that you can get ciliastasis, animal exposures.

We can further demonstrate that the materials that cause that effect in the animals are absorbed in the oral

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cavity of man and other investigators have published indicating there isn't a significant cilia static affect in the average smoker.

Q. When was the first time that Lorillard determined that you could determine in animal studies the ciliastatic affect of smoking?

MR. ALLINDER: Object to form.

THE WITNESS: We were studying this back in the early 1960s.

BY MR. HEFTER:

Q. Is that when the company first determined that you could demonstrate ciliastatic effect in animal studies?

A. In these bioassay systems that we had developed and at the time it was the -- the early ones were the clam and the frog and the rabbit and the cat.

Q. Is the results of those studies in the early '60s reflected in the article written by, authored by you, Rylander and Dalhamn?

A. Some of that, yes, and some of the other work that was done by Rylander and Dalhamn in their laboratories was also published, but I wasn't an author, but it was work sponsored by Lorillard.

Q. Turn to page three of your expert report. I will refer you to the first full paragraph where it states I may testify about research Lorillard has sponsored or conducted

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in-house on smoking health issues including research related to the chemical composition of cigarette smoke.

Do you have an expert opinion of the research that Lorillard has sponsored or conducted in-house on smoking and health issues including research related to the chemical composition of tobacco smoke?

A. Yes, I have an opinion. I mean, it was high quality research that was conducted over time of a program trying to identify components of tobacco smoke, particularly those that might have a biological activity, that is, cause a response in a bioassay system. This ranges from the early work on benzo(A)pyrene and then we had studies developing methods for determination of phenols, which at the time were thought to be promotors in the mouse skin, promotors of carcinogenesis, and also were thought to have some role in the ciliastasis in these bioassays we were using.

We went on to look and identify many compounds that were in some of these fractions that we generated that were painted on mouse skin, and published the results in terms of what we were identifying. That led to some of the mouse skin painting experiments that I already described where we were testing some mixtures of compounds that we found to be present in tobacco smoke. That would be I think the nature of the testimony.

Q. I may have asked you this before, if so, I

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apologize. Has Lorillard ever published any article or written statement to the public that any particular compound in tobacco smoke is known to be an animal carcinogen?

MR. ALLINDER: Object to the form.

THE WITNESS: Specifically stating that this compound is in tobacco smoke and is an animal carcinogen?

BY MR. HEFTER:

Q. Correct.

A. I don't think so.

MR. ALLINDER: Same objection.

BY MR. HEFTER:

Q. Are you aware that over the course of the same period of time from the early '60s to the present that there exists scientific literature which have concluded that particular compounds in tobacco smoke are known to be animal carcinogens?

A. Yes.

Q. We talked about animal skin painting experiments as well as animal inhalation experiments. Can you identify any other types of bioassays that Lorillard has used to determine the chemical composition of cigarette smoke?

MR. ALLINDER: Object to the form.

THE WITNESS: I don't understand your question. I understood you to say what other bioassay systems has Lorillard used to determine the composition of tobacco smoke?

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BY MR. HEFTER:

Q. Correct.

A. You don't use bioassays to determine composition.

Q. Can you identify for me -- other than skin painting experiments or the animal inhalation studies, can you identify for me any bioassays that Lorillard has used to determine the carcinogenicity of any chemical compound used in tobacco smoke?

MR. ALLINDER: Object to the form.

THE WITNESS: We have used and I think continue to use most of these, but we have a program of evaluating additives, potential additives to tobacco, and we start out with a series of short term tests. Among those are the Ames mutagenic tests. There are tests to determine whether or not you affect the immuno-competence of the test system by a specific component that you are testing or ingredient that you are testing. There are tests that try to determine whether or not there is any cardiovascular effects.

Actually, I think there are additional mutagenic tests including cystochromagenic exchange is another we have used, and I think we may still use. Then we get to the longer term, there is a longer term inhalation study and the mouse skin studies which we thought to be and I'm sure I'm not covering all the individual tests we have used or continue to use in this evaluation scheme, but those are the

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ones that occur to me at the moment.

BY MR. HEFTER:

Q. There is just one that I just didn't hear properly.

MR. ALLINDER: Cystochromagenic exchange is that the one where your eyebrows went up, is that right?

MR. HEFTER: If you saw my eyebrows go up, you are probably right.

MR. ALLINDER: That's one you don't have notes on?

MR. HEFTER: That's correct.

THE WITNESS: I recalled another we have used is early hydrocarbonhydroxylate activity.

BY MR. HEFTER:

Q. Have you used these tests, the ones you just noted, to determine whether or not any part particulate in tobacco smoke or any compound, chemical compound in tobacco smoke is or is not carcinogenic?

MR. ALLINDER: Object to the form.

THE WITNESS: I don't recall that, but that's not the basic purpose of the test. It's to determine whether or not a potential additive to tobacco is suitable from our point of view with respect to its toxicology.

BY MR. HEFTER:

Q. Other than the experiments that you just -- the types of experiments that you just noted and the skin painting experiments and the animal inhalation studies, can

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you think of any other type of experiment that Lorillard employs or has employed in its research activities?

MR. ALLINDER: Object to the form.

THE WITNESS: No, I think that that covers everything that occurs to me now.

BY MR. HEFTER:

Q. I would like to turn your attention to the next paragraph in your report which is the second full paragraph on the page. I refer your attention to the last sentence of the paragraph where you state I may also testify concerning Lorillard's efforts to modify its products over the years?

A. Yes.

Q. Do you have an expert opinion as to how Lorillard -- strike that.

Do you have an expert opinion regarding Lorillard's efforts to modify its products over the years?

A. Yes. I know what modifications have occurred, and I know what generally the scientific community -- there was knowledge in this area was suggesting with respect to product modifications over time, and basically what Lorillard did in some of its research activities in response to those kind of opinions and communications in the scientific community.

Q. What is your opinions with respect to that?

A. Well, on some of it I already talked about, but in response to the skin painting activity in the early 1960s

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some, particularly with Dr. Wynder's laboratory and then some of the confirmation in Homberger's laboratory, we adopted the use of reconstituted sheet which had a lower response of condensate from which had a lower response on mouse skin.

Also, in the early 1970s we started to include, expanded tobacco into our products and this too shows a lower response on mouse skin condensate from it. This was all confirmed again to us with the tobacco working group activities where they conducted mouse skin painting experiments on these same materials.

Over time there was a feeling that if you could increase the porosity of paper and that sort of thing, that this would reduce possibly reduce activity on mouse skin, but more importantly, it became a technique of general reduction in terms of tar and nicotine, and we have adopted more porous papers and more efficient filters, including ventilation which allowed you to reduce paper paste components that are not reduced by conventional type of filters without ventilation.

Again, all these areas have been researched and adopted into most of our brands. As I indicated, much of this is consistent with a direction that came out of the tobacco working group activity and the direction that was being promoted by Dr. Gori at the time.

Also, in that same time frame there were

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suggestions that people smoked for nicotine, and therefore, if you could maintain the level of nicotine and reduce tar selectively, tar being the other components and thought to be those that produced a response on mouse skin, that this would be a "safer cigarette."

We conducted a research program that was aimed at the possibility of trying to do that. That same proposition was advanced by some folks in the UK as well in that same time frame. It was kind of a group of public health related people were kind of advocating that as a possibility of making a safer cigarette.

I would describe these things in terms of my opinion on this.

Q. I understand that that is --

MR. ALLINDER: May I interrupt you for just a moment. I apologize for this. I think there may have been miscommunication between you and Dr. Spears a couple of minutes ago I want to point out to you. You were asking before with respect to this earlier paragraph regarding different types of experiments that were conducted by Lorillard in its research facilities, and I think you were asking him about bioassays, and then changed to other types of experiments. I think Dr. Spears' testimony was listing the types of bioassays that were employed, but to the extent that you asked or understood this question to deal with other

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types of experiments, then I think there may have been a miscommunication and I would have to have the question and answer read back, but I think that when you got to the end of the question you were talking about bioassays and then you changed to whether there were any other types of experiments conducted by Lorillard, and I think Dr. Spears was still thinking about bioassays.

If I have interrupted you and there is not a misunderstanding between you and the witness, I apologize for that, but I think there may have been.

MR. HEFTER: There may have been, I don't know. When you refer to the bioassays, are you referring to the list where he went down to the Ames mutagenic test, immuno -- I can't read my handwriting and then to the immuno-competence.

MR. ALLINDER: You were asking questions with respect to the first full paragraph on page three of the expert report dealing with chemical composition and the series of questions dealing with bioassays that have been investigated or employed by Lorillard, and then I think you went back to a question having to do with whether there were any other types of experiments and Dr. Spears said no, but I think he was thinking in terms of bioassays and not other types of research that would be considered non-bioassay, and again, if I have -- if there wasn't a misunderstanding

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between you and the witness I apologize for the interruption.

BY MR. HEFTER:

Q. Let me since now I think probably all three of us are thoroughly confused, let me try to ask a few follow-up questions there.

Since I don't remember exactly what the record states and the record will reflect itself, let me do it this way.

MR. ALLINDER: If this would be easier perhaps you and I could go back and look at that question and answer and I don't want to change your focus.

THE WITNESS: I know what my answer was. I thought I was answering a question are there any other bioassay systems that were used other than mouse skin painting and the animal inhalation.

BY MR. HEFTER:

Q. And the answer to your question was no, is that correct?

A. It was a list I gave you.

Q. And other than the list that you provided and the animal inhalation studies and the skin painting studies, are there any other studies whether bioassay or any other type of studies that Lorillard has conducted to determine the carcinogenic, mutagenic or tumorigenic affect of tobacco smoke?

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A. I think the answer is no, there aren't any other studies that I can think of that would be other than bioassay for that determination or in vitro cellular types.

Q. Just to give you a point of reference, I think we had then skipped to the subject of your opinion regarding Lorillard's efforts to modify its products over the years and you proceeded to give me a list of ways in which you have changed the design of your product, is that correct?

A. That's correct, and some of the reasons for those changes.

Q. But do you have an opinion of Lorillard's efforts to modify its products over the years?

A. I think the efforts that were made were consistent with the data that we had, consistent with the data that other investigators had generated, including the tobacco working group, and I think that our response is in the changes that we incorporated were state of the art and done in a timely fashion.

Q. Has Lorillard ever marketed a cigarette that eliminated any chemical compound found in tobacco smoke?

MR. ALLINDER: Object to the form.

THE WITNESS: Eliminated is not really a definable term. It depends on the method of the analysis. You can get more and more sensitive methods. We have certainly marketed cigarettes with reduced levels of many compounds, but

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absolute elimination, I don't think so.

BY MR. HEFTER:

Q. Does Lorillard today market any unfiltered products?

A. Yes. We have one unfiltered product, Old Gold Straights, which is a very, very minor brand.

Q. Other than Old Gold Straights, do all of Lorillard's cigarette brands employ all of the mechanisms that you just described?

MR. ALLINDER: Object to the form.

THE WITNESS: All except the degree of ventilation varies among the brands, ventilation being highest on the low tar yield brands and virtually absent on the higher tar yield filter brands.

BY MR. HEFTER:

Q. Other than the design changes that you just described, has Lorillard implemented any other design change in any cigarette that it markets?

MR. ALLINDER: Object to the form.

THE WITNESS: We have changed I guess some of the additives over time for various reasons, the primary reason being trying to improve the acceptance of the product in the marketplace.

There have been changes in tobacco that's grown over time and there have been changes in the percentage of

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the types of tobacco that we use by brand over time, again trying to improve the acceptance of the product. There has been a general reduction to near elimination of persistent pesticides as used by the farmers.

BY MR. HEFTER:

Q. What kind of pesticides?

A. Persistent. Those are the other changes that occur to me that I would list.

MR. HEFTER: Why don't we go ahead and take a five minute break.

(Recess was taken from 3:54 p.m. to 4:08 p.m.)

BY MR. HEFTER:

Q. If I can turn your attention, Dr. Spears, to page four of your report. You used the phrase in your report safer cigarette, which is on the carryover sentence on top of the page?

A. Yes.

Q. Do you see that? What is your understanding of the term "safer cigarette" in the context of this litigation?

MR. ALLINDER: Object to the form.

THE WITNESS: It would be a cigarette that based on bioassay systems would appear to be a safer cigarette.

BY MR. HEFTER:

Q. Have you ever heard the term denicotinized cigarette?

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A. Yes, I have.

Q. What is your understanding of the term denicotinized cigarette?

A. A cigarette with essentially zero nicotine. Maybe a better definition would be substantially reduced nicotine in the tobacco.

Q. Has Lorillard ever marketed a denicotinized cigarette based on the definition that you just provided?

A. No, we have not.

Q. Has Lorillard ever test marketed a denicotinized cigarette based on the definition that you provided?

A. No, Lorillard has not.

Q. Have you ever heard of a product called Premier?

A. Yes, I have.

Q. Can you describe for me what Premier was?

A. It's a competitor's product, namely RJR. It was a product that did not burn tobacco but contained a chamber that allowed the generation of an aerosol that contained nicotine, glycerin and presumably some flavoring materials. Each source was a charcoal type tip, which smoldered and then provided the heat source to generate the aerosol. It was test marketed by the company in probably about late '80s, maybe, early '90, late '80s, I think.

Q. Did Lorillard Tobacco -- strike that.

Has Lorillard Tobacco ever tried to develop a

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product using the aerosol technology similar to Premier?

A. No, we have not.

Q. Can you describe for me what Next was?

A. That's a Philip Morris product, and my understanding is that the nicotine was removed by a process that's used to remove caffeine from coffee, which was available to them in their, I guess, the food organization, their food subsidiary. It was market or at least test marketed in probably again about maybe eight years ago.

Q. Did Lorillard -- has Lorillard Tobacco ever attempted to develop a cigarette using the same technology as that was employed by Philip Morris in connection with Next?

A. We have worked in the laboratory on technology to reduce nicotine.

Q. Let me ask my question again. Has Lorillard Tobacco Corporation ever developed a product using the same type of nicotine reduction technology that was used by Philip Morris in connection with Next?

MR. ALLINDER: Object to the form.

THE WITNESS: No, we have not developed a finished product.

BY MR. HEFTER:

Q. Do I take it then from your answer that you have not test marketed a product using that technology?

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A. That's right, we have not developed a commercial product.

Q. Are you familiar with a product called Eclipse?

A. Yes, I am.

Q. Can you describe Eclipse for me?

A. Very similar to the Premier, although it has some tobacco in it that is burned, a small amount of tobacco.

Q. Do you know which company developed the product?

A. RJR.

Q. Has Lorillard ever developed a product based on the technology used by RJR in Eclipse?

A. No, it's the same technology as the Premier basically.

Q. Do you know of a product called Fact?

A. Fact is a product of quite sometime ago as I recall.

Q. Can you describe for me your recollection of the Fact product?

A. My best recollection is that this was test marketed by Brown & Williamson, and I'm not 100 percent sure I'm right, but I believe it was a product that had some additives in the paper that caused holes to open so that you got increased ventilation as you smoked the cigarette.

Q. Was the product test marketed by Brown & Williamson?

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A. I believe that's correct, yes.

Q. Do you know when it was test marketed by Brown & Williamson, approximately?

A. I'm guessing, but 15 years ago.

Q. Do you know if Brown & Williamson used that technology in any other brand that it was selling?

A. Not that I'm aware of, and I'm a little foggy as to whether this was a technology as I described it.

Q. Has Lorillard ever developed a product based on the technology used by Brown & Williamson that was used in Fact?

A. No, we did not.

Q. Do you know -- have you ever heard of something called BAT Flake?

A. I have heard the word, yes.

Q. What is your word of the what is your understanding of the term BAT Flake?

A. That it is a reconstituted sheet developed by BAT.

Q. Do you understand BAT Flake to contain charcoal?

A. I don't have detailed understanding of the composition of this. I believe it may have been a non-tobacco material.

Q. Has Lorillard ever marketed a product using non-tobacco material in its cigarettes?

A. No, but Lorillard investigated these in terms of laboratory and also in cooperation with the National Cancer

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Institute.

Q. Can you did he describe for me the investigation?

A. There were two products that were investigated. One was called NSM for new smoking material and it was produced by I believe it was Imperial Chemical in the UK and one that was produced by Celanese in this country. Both were synthetic smoking materials.

We evaluated them in terms of animal studies, in terms of using them as diluents to tobacco and they were also carried into the tobacco working group program and evaluated there, again, both as I think a mixture with tobacco and also in 100 percent forms and the conclusions were that the results on mouse skin painting on an equal condensate level were not different for these materials than they were for tobacco.

Q. Did Lorillard conduct these experiments -- when I say experiments, the mouse skin painting experiments on the NSM and the Celanese product in-house?

A. No.

Q. Who conducted the mouse skin paintings on NSM and the Celanese product?

A. Certainly they were conducted in the tobacco working group experiments and that would have been at Hazleton Laboratories, and I believe Homberger conducted -- may have conducted these experiments and they may have been

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funded not by Lorillard, but by the respective organizations that produced them.

Q. The Hazleton laboratory, is that based in England?

A. There is a Hazleton laboratory in England but the one I'm referring to is here in this country.

Q. Where is that located?

A. It's in the Washington, DC area.

Q. Based on the results of those studies, I take it that Lorillard has never developed a tobacco product using NSM or the Celanese product?

A. That's correct.

Q. Have you ever heard of a product called Accord?

A. Yes, I have.

Q. Can you describe for me what your understanding of Accord is?

A. It's a product by Philip Morris which they test marketed. It's a small tobacco rod, if you will, that has tobacco wrapped in paper that you insert into an electrically energized device that causes a low temperature heating of the tobacco as you puff on it while it's in the device.

Q. Has Lorillard ever developed a cigarette based on the technology used in the Accord product?

A. No, we have not.

Q. Has Lorillard Tobacco ever developed a product using any other type of alternative delivery system?

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MR. ALLINDER: Object to the form.

THE WITNESS: We have not developed a product for commercial, a commercial product, no.

BY MR. HEFTER:

Q. Have you developed any products using alternative delivery system on an experimental basis?

A. Yes, we have worked on products. One was a product that had a hole down the center of the product, which kind of burned in a reverse fashion at much higher temperatures than tobacco normally burns, producing a very different cigarette smoke condensate, and we investigated that product, not only possible ways to fabricate it, but also a fair amount of detail in smoke composition. That was one research activity. We have had --

Q. Let me stop you for a second. Did that product with the hole down the center have a particular name within Lorillard?

A. It had a project name, but I don't remember it right now. I was going to say we have looked at modifications you might make in reconstituted sheet that we alter products. I have already discussed generally the fact that we had a project related to reducing nicotine, and one reducing tar and maintaining a level of nicotine. These are some of the altering designs that we certainly looked at over time.

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Q. The product with the hole down the center, did Lorillard ever test market that product?

A. No, we did not.

Q. Would you agree that the FTC smoking machine does not accurately measure tar and nicotine yields that are ingested by a human under smoking conditions?

MR. ALLINDER: Object to the form.

THE WITNESS: No, it does not. It's not possible to have a single mechanical smoking procedure that represents all human smokers. People smoke in very different ways and the best you can do is say this is representative, it's in the range of human smoking behavior, and I believe the FTC machine is in the range of human smoking behavior.

BY MR. HEFTER:

Q. And what's the basis for your conclusion in that regard?

A. There were surveys done in terms of how people smoke, in terms of puff volume, in terms of puff duration, in terms of puff intervals. I have reviewed that literature in the past and it's generally referred to as topography of smoking. I guess you might say the average puff -- there is quite a variation. The average puff is probably around 45 milliliters. The FT smoking procedure called for 35. It's certainly in the range of variation that you see in human smoking.

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The puff duration of two seconds is reasonably typical of the average. It's around that two seconds, maybe 1.9 or 1.8, 2.2, something like that. So it is certainly representative. The puff interval in the mechanical machine is one puff per minute or 58 seconds, and the human behavior on average is probably more like 35 seconds or 40.

So I would say that that procedure is representative of human smoking. It's been adopted as the standard for generating cigarette smoke for analytical and bioassay procedures. So it represents a basis on which you might compare between laboratories and that sort of thing all using the same standard method for smoking. But there is no exact number that's representative of your smoking or mine because I may take a puff every 15 seconds or I may let it sit in the ashtray and take a puff once every minute or minute and a half. The same thing is true with puff volume, it varies dramatically by individuals.

Q. Isn't it true that puff volume changes when an individual changes from a higher yield cigarette to a lower yield cigarette?

MR. ALLINDER: Object to the form.

THE WITNESS: That has been reported, that the puff volumes are larger for low delivery cigarettes, yes.

BY MR. HEFTER:

Q. Has Lorillard conducted any studies to determine

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whether puff volume is larger when an individual changes from a higher yield cigarette to a lower yield cigarette?

A. We believe that the literature on this subject, including any data we would have indicates that there is some compensation or some change in smoking behavior if a person moves from one higher -- let's say higher nicotine, higher tar brand to a lower tar, low nicotine brand, a fairly dramatic shift in yield by the mechanic machine. But there is some compensation or compensatory effects. Much of it is short term and we believe the individual goes back to their more normal smoking pattern that they are most accustomed to.

Q. What is your basis for that statement?

A. General review of the literature.

Q. Can you identify any specific literature that has included that individuals go back to their previous smoking behavioral styles on a long term basis?

A. There is a book which is published not long ago and I think it's -- I can't remember the title, but it was published probably about a year ago which summarizes this and summarizes much of the literature on the subject.

Q. Other than this book, can you identify anything --

A. It is a summary of the articles that appear in the scientific literature. I can certainly -- I can't recite them now, but --

Q. Do you recall who the author of this book was?

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A. That's what I'm trying to remember. I think the book is something like Tobacco and Technology or something like that, and I believe one of the editors may be Layten Davis.

Q. Layten is L-a-u-t-o-n?

A. L-a-y-t-e-n.

Q. Who is Mr. Davis?

A. He was previous -- he was at one time I think the North Carolina Department of Agriculture, then to the Kentucky Tobacco and Health Institute and most recently at Reynolds Tobacco.

Q. Can you identify any article in the scientific literature that's been published by any individual not affiliated with any tobacco company that individuals revert back to their previous smoking styles on a long term basis?

MR. ALLINDER: Object to the form.

THE WITNESS: I don't think I said they go back to their styles totally. I said they compensate but then they reduce their compensation, more in the direction of their former smoking styles. Most of that is based upon measuring nicotine metabolites in the body fluids or urine of smokers who switched to different products.

BY MR. HEFTER:

Q. And the basis for your previous statement is the book by Layten Davis?

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MR. ALLINDER: Object to the form.

THE WITNESS: No, that's one reference, but I'm saying there are references in the literature. I can't recite them for you right now.

BY MR. HEFTER:

Q. Have you ever conducted any research experiments on smoker compensation yourself?

MR. ALLINDER: You meaning Dr. Spears personally?

MR. HEFTER: Yes.

THE WITNESS: No.

BY MR. HEFTER:

Q. Would you say that you keep up-to-date with the scientific literature in connection with smoker, the issue of smoker compensation?

A. Yes.

Q. Are you aware of any studies, short term or long term, which have concluded that there is no compensation when an individual changes from a higher yield to a lower yield cigarette?

A. No, I am not -- well, I think there are some studies which suggest there is very little compensation, but I don't think there is any that say there is no compensation.

Q. Do you agree that individuals -- strike that.

Isn't it true that individuals compensate by smoking more cigarettes when changing from a higher yield to

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a lower yield cigarette?

MR. ALLINDER: Object to the form.

THE WITNESS: I think the data is that there may be a small increase in number of cigarettes smoked per day, but that is not the primary mechanism of compensation.

BY MR. HEFTER:

Q. What is the primary mechanism of compensation in your view?

A. Larger puffs.

Q. Isn't it true that puff interval -- let me repeat that.

Isn't it true that the scientific literature demonstrates that puff intervals increase when an individual changes from a higher yield cigarette to a lower yield cigarette?

A. There may be. I can't recall that specifically. I recall that the primary mechanism is larger puff volumes. If an individual increases their puff frequency in any measurable way, they are going to consume the cigarette much more quickly, and I think this leads to a rejection of the product if you are not deriving on a per puff basis whatever experience and taste and what have you that you expect and if you have a cigarette that burns up very quickly, this is usually rejected. We get complaints of cigarettes that burn quickly.

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Q. Can you identify any article that has been published in any scientific journal since January 1, 2000 that has addressed the issue of smoker compensation?

A. I'm not sure of the publication date, but I think there was one recently out of the American Health Foundation which described some of their work on smoker compensation.

Q. And can you tell me the conclusions reached by the American Health Foundation in that article?

A. I believe they are consistent with what I said, the puff volume has increased, the primary mechanism of compensation. There may be some reduction in puff interval.

Q. Do you recall having read this article in the American Health Foundation that was published by the American Health Foundation?

A. It was published by an investigator there and it's a woman and her name escapes me, although I do recall it's a northern European name.

Q. Do you recall reading the article by this woman?

A. Yes.

Q. Did you agree with the methodology that was employed by the woman in reaching her conclusions?

A. It has some of the same problems, some of the other work done. This was short term switching between products. You have a person in a laboratory environment where they are fastened up to some apparatus which makes these measurements.

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So it's not exactly the kind of situation you have in the field. It's artificial in the sense that you have this apparatus connected up to the person smoking the cigarette.

Q. Any other criticisms that you have with this work?

A. Yes, you can make the measurements, there is no question about that. The question is, are they really representative of what's happening in the field.

Q. Do you believe that her measurements were accurate based on the studies that she -- based on the subjects she looked at?

A. I have no reason to doubt the data she collected. All I'm questioning is relevance of it.

Q. Isn't it true that individuals who smoke lower yield cigarettes will intake a greater amount of nicotine and tar per cigarette than is reported on the cigarette pack based on the FTC method?

MR. ALLINDER: Object to the form.

THE WITNESS: Some people certainly do, but I think that's also true of the higher yield cigarettes as well.

BY MR. HEFTER:

Q. Can you identify any study in the scientific literature that individuals who smoke lower or higher yield cigarettes intake the exact same or less than what's reported on the cigarette package by the FTC method?

A. No. I think I told you earlier that the average

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smoking topography that I reviewed not very many years ago would indicate the average in terms of puff size as being larger than the FTC procedure, that the interval between puffs to be shorter, that the puff duration is very much like the average in the FTC method, but there is tremendous variation among smokers. So the average really doesn't mean anything to an individual smoker, and it's as meaningful to report in terms of a relative sense measurements according to the FTC smoking parameters as it is to report some other smoking parameters.

The relative ranking of brands seems to be similar regardless of which mechanical smoking procedure you use as long as you use the same procedure for each product, each brand.

Q. Has Lorillard Tobacco Company ever informed smokers publicly that the amount of nicotine and tar that they are intaking per cigarette may be different than what's reported on the cigarette package by the FTC method?

MR. ALLINDER: Object to the form.

THE WITNESS: No, but I think to me that's obvious as well as the number of cigarettes you smoke. If you smoke more cigarettes than some other individual and smoke them in the same way you are going to get more tar than the individual who smokes fewer cigarettes. It seems pretty obvious if you are going to smoke cigarettes in a way that's

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different than the mechanical smoking machine then you are going to get a different yield.

BY MR. HEFTER:

Q. But Lorillard Tobacco Company has never publicly stated what you just said?

MR. ALLINDER: Object to the form.

THE WITNESS: No, we have not, to my knowledge, stated that to the public.

BY MR. HEFTER:

Q. Has Lorillard Tobacco Company ever conducted any epidemiological tests to determine whether the incidence of lung cancer has decreased as a result of low tar and low nicotine cigarettes?

A. Lorillard hasn't conducted any such study, no.

Q. It is true, is it not, that individual smokers can block ventilation holes with their fingers and lips, is that correct?

A. It's been asserted -- our evidence would be that there isn't any significant blocking, and even if there is, you don't change the yield of the cigarette very much unless you have a very, very large percentage of holes blocked.

Q. What do you mean when you say our evidence shows?

A. Well, we have looked at studies where we tried to determine how far an individual inserts a cigarette in their mouth as to whether they would be blocking holes, and that's

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done just by walking up to a smoker in our corporation and just catch them in a moment they are taking a puff and take the cigarette and make a measurement as to how far they inserted it.

We have also tried to do experiments where you determine how much the lips have covered the cigarette, tipping paper as to whether it covers over the holes. There have been some difficulty with those type of experiments because the way you try to visualize how much the lip has occluded the holes or potentially occluded them is by making a colorimetric measurement on the aminoacid with the residue that the lips leave.

Reynolds has published in their investigations on this subject and find very little occlusion as well. We have also taped part of the holes to see how much it changes the yield, and say, unless you really occlude a large percentage of them you don't change the yield of the cigarette that much. So I think it's kind of a misrepresentation or kind of an idea that some people thought might be happening and they based it on highly verticulated cigarettes have kind of an unusual pattern on the filter if ventilation is there. The stain is more in the center and it was through that observation that people made the conjecture that this was happening.

To the best of my knowledge, it happens very

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limitedly.

Q. Can you identify any scientific article that you have reviewed within the past year on the subject of ventilation hole blocking?

A. I just referenced one which was from Reynolds. I don't remember the name and date of the publication, but using the technique of measuring where the staining on the tipping paper occurred as a result of the lips.

Q. Any others?

A. Well, there have been a number of papers. I think also in our own laboratory the measurement of how much hole blocking you have to do to really change the yield of the cigarette is also important.

Q. Any others?

A. Not that I recall at the moment.

Q. Other than this paper by the woman who has a European name, can you identify any article on the subject of -- any other article on the subject of smoker compensation that you have reviewed within the past year?

A. The book that I'm referring to has a section on smoker compensation, which again is kind of a summary of the literature. There have been studies -- well, certainly the Surgeon General's, last Surgeon General's report I think has something on this. I don't remember when I reviewed it last, but smoker compensation ideas and hole blocking has been

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around and debated for a number of years. But right now I cannot recite the papers that I have reviewed.

Q. Has Lorillard Tobacco Company ever publicly told smokers that lip blocking and finger blocking can affect nicotine and tar yield?

MR. ALLINDER: Object to the form.

THE WITNESS: No, I just said to you I don't think it does affect it very much.

BY MR. HEFTER:

Q. Is your testimony that there is zero?

A. I didn't say zero. I said you have to block a large percentage of the holes to have a significant change in the yield on the mechanical smoking machine.

Q. And the basis for your opinion in that regard is the literature published by Reynolds and your own internal studies, is that correct?

MR. ALLINDER: Object to the form.

THE WITNESS: That's correct. Yes, those are our own internal studies, how much blockage you have to do to get a major change.

BY MR. HEFTER:

Q. Do you know what the death rate from lung cancer is in the United States from 1960 to 1966?

MR. ALLINDER: Object to the form.

THE WITNESS: Do I know the death rate in terms

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of -- are you talking about number of lung cancer deaths per thousand by year from 1960?

BY MR. HEFTER:

Q. Correct, from 1960 to '66?

A. For all age groups combined?

Q. Correct.

A. I can't recite it. I know generally it's been in the neighborhood of 100 per 100,000.

Q. Do you know what the death rate for lung cancer --

A. I'm sorry, I thought that's what we were talking about, lung cancer.

Q. I'm going to ask you for a different time period now, same parameters from 1982 to 1989?

A. No. I have not memorized these numbers.

Q. At any time do you recall seeing statistics on death rates from lung cancer?

A. Yes, certainly.

Q. Do you know if the death rate per thousand for lung cancer was higher in the 1980s than it was from the period of 1960 to 1966?

A. It's normally reported per hundred thousand, but it's different for men than women, and as I say, I can't recite the details. I can tell you there was an increase in trend in that period for men and men tend to flatten out and women have been increasing.

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Q. Isn't it true that there are studies in the scientific literature that there is significant compensation, smoker compensation when an individual changes from a higher yield cigarette to a lower yield cigarette?

A. You asked that question. Yes, there are studies in the literature that report that. There are other studies that report there is some compensation, but it's not total compensation.

MR. HEFTER: Give me a minute and I will see what else I have.

MR. ALLINDER: You want to take a break or do it?

Mr. HEFTER: Yes.

(Recess was taken from 4:53 p.m. to 5:07 p.m.)

MR. HEFTER: Let's mark this as the next exhibit. Let me mark for the record Spears Exhibit No. 6.

(Exhibit No. 6 marked for identification.)

MR. ALLINDER: Give me an opportunity to look at this, please, before you ask a question.

BY MR. HEFTER:

Q. At the same time, Dr. Spears, why don't you do the same.

A. All right.

MR. ALLINDER: I note for the record the objection od defendants to the use of this document because it is privileged.

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MR. HEFTER: Your objection is noted.

MR. ALLINDER: You may continue.

THE WITNESS: All right.

BY MR. HEFTER:

Q. Have you ever seen this document before?

A. No.

Q. Who is Mr. Arrensfeld?

A. I believe Arrensfeld was an attorney for Philip Morris.

Q. Do you know who Mr. Greer is?

A. He was an attorney representing Liggett Meyers.

Q. Do you know who Mr. Crohn is?

A. An attorney representing Reynolds.

Q. And Mr. Henson?

A. I believe American.

Q. And Mr. Stevens was the general counsel of Lorillard?

A. Lorillard, uh-huh.

Q. Is that correct?

A. That's correct.

Q. Would it be fair to say that those five gentlemen at the time were the Committee of Counsel?

A. I don't know.

Q. Did you have any discussions with Mr. Stevens at the time in or around March of 1978 regarding the FTC smoking

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machine for carbon monoxide analysis?

A. I don't recall any.

Q. Do you know at the time in 1978 whether the FTC was considering testing for carbon monoxide in its -- in the use of its smoking machine?

A. I don't know the exact timing, but the Federal Trade Commission did begin to analyze and report carbon monoxide.

Q. Do you recall when the FTC started reporting on carbon monoxide content in cigarette smoke?

A. I do not. I do recall a discussion about the machine, that the specifications they gave to the manufacturer, which I think some of us felt we were unnecessary, and this was the ability to measure carbon monoxide on a puff by puff basis.

Q. Do you recall whether Mr. Stevens asked you to perform the carbon monoxide test that I referred to in the fourth paragraph of this document?

A. I don't know. I don't know.

Q. Do you know if the research department at Lorillard Tobacco ever conducted carbon monoxide tests that are referred to in this paragraph four?

A. I don't know if we conducted tests referred to in this paragraph but we have been conducting carbon monoxide -- it's been included in our smoking procedure measurements,

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routine for quite a long time.

Q. Do you recall if the research department at Lorillard Tobacco forwarded the results of any test to Covington & Burling?

A. I do not.

Q. Do you know if Covington & Burling submitted any information or analysis to the FTC pointing out any deficiency in any carbon monoxide testing program?

A. I simply recall the belief on our part that the puff by puff analysis was a waste of money and energy and in terms of specifying that ability with a machine that they were proposing to purchase.

Q. Why in your view was it a waste of time and money?

A. Because they were going to report it on a per cigarette basis.

Q. Why would that be a waste of time or money?

A. Because you make one measurement on a per cigarette basis and you make ten measurements, so if you do it on a per puff basis the cost of making a measurement goes up dramatically if you want to do it on a per puff basis in terms of design of that machine to do that.

Q. And your recollection is that they wanted to do it on a puff by puff basis?

A. That's correct, and they started out that way and ultimately abandoned it as an expensive approach that they

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discontinued.

Q. And they ultimately decided to determine carbon monoxide based on a per cigarette basis?

MR. ALLINDER: Object to the form.

THE WITNESS: That's right, and that's the way it's reported now.

BY MR. HEFTER:

Q. Is that reported to smokers on cigarette packages?

MR. ALLINDER: Object to the form.

THE WITNESS: I don't think it's mandatory. It is in the advertising materials for the cigarette, yes.

BY MR. HEFTER:

Q. But on the signature package itself, the ones that Lorillard, cigarettes that Lorillard markets, it does not contain the per cigarette CO content?

A. I don't think so. I don't think it contains tar and nicotine per cigarette either on the package.

Q. Who is Mr. William Shinn?

A. An attorney with Shook, Hardy.

Q. Do you know why the attorneys were involved in responding on behalf of the industry regarding the FTC's consideration of carbon monoxide analysis?

MR. ALLINDER: Object to the form.

THE WITNESS: No, I don't particularly know other than obviously it was going to potentially generate a new

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reporting requirement.

BY MR. HEFTER:

Q. You mentioned earlier that Lorillard had conducted studies to determine how far an individual put cigarettes into their mouth, is that correct?

A. Yes, we had a study done.

Q. Was there a research report generated based on that study?

A. Internal report, I think so.

Q. Was that internal report published in any journal?

A. No.

Q. The subjects of that study were only Lorillard employees, is that correct?

A. That's correct.

MR. HEFTER: Mark this as the next exhibit.

(Exhibit No. 7 marked for identification.)

MR. ALLINDER: Give me a moment to look at this, too, please.

MR. HEFTER: Why don't we go ahead and change the tape then.

(Recess was taken from 5:15 p.m. to 5:16 p.m.)

MR. ALLINDER: I will note for the record defendants' privilege objection to the use of this document.

MR. HEFTER: The objection is noted for the record.

Have you had an opportunity to look at the

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document, Dr. Spears.

THE WITNESS: I have, yes.

BY MR. HEFTER:

Q. Have you ever seen this document before?

A. I don't believe so. Yes, I am copied on it. I must have seen it.

Q. Sitting here today, do you have a specific recollection of seeing it, this particular document?

A. No, but I recall the subject.

Q. Who is Mr. Wakeham?

A. He was the research and development vice president for Philip Morris.

Q. Was he -- in 1969, did he hold the equivalent position as you did at Philip Morris?

A. Yes, I believe that's correct.

Q. Do you know who Mr. Topol is?

A. Yes, I do.

Q. Have you had an opportunity to personally meet Mr. Topol?

A. Yes, I have met Mr. Topol.

Q. Who is Mr. Topol?

A. An attorney at Covington & Burling.

Q. What capacity did you have to meet Mr. Topol?

A. He attended some meetings, I guess, that I attended at The Tobacco Institute and other locations I think where

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there was some gathering of industry people and he was playing the role of making sure there was no antitrust activity.

Q. Do you recall when that particular meeting at The Tobacco Institute was held?

A. I think there were -- there was certainly a meeting around this subject that took place.

Q. Who is Mr. Bennett?

A. Bennett.

Q. Mr. Word B. Bennett, do you recall?

A. Yes. He was with U.S. Tobacco, the research person.

Q. Would it be fair to say that the other individuals who are CC'd on this document are researchers at particular tobacco companies?

A. They are.

Q. Do you recall having any discussions with Mr. Stevens regarding the particular issues that are raised in this letter?

A. I don't recall Brooks George being a researcher.

Q. Was he an attorney?

A. I don't think so.

Q. Do you know what company he worked for?

A. One of the smaller, small companies. I think he may have been the chief executive.

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Q. It says -- right after point two in the paragraph it starts it has been agreed?

A. Yes.

Q. For the manufacturer of the cigarettes that the P. Lorillard Company would prepare the strips of tobacco blended into proper proportions to match the Kentucky reference cigarette formula. Did I read that portion of the sentence correctly?

A. You did.

Q. Can you tell me if Lorillard prepared the strips of tobacco pursuant to what's stated in this letter?

A. I can't recall, but I think we were participating in this study and that was our assignment, so I think we carried it down.

Q. What was the purpose of the study?

A. To evaluate an innovation that was brought to the industry and also came to Lorillard independently. The invention was asserted that it would reduce the benzo(A)pyrene in tobacco smoke and also to reduce the tumorigenicity in mouse skin bioassay.

Q. If you recall, why was it necessary for more than one company to be involved in the testing procedure?

A. Sharing in the expense of the mouse skin testing.

Q. What were the results of the mouse skin testing of the Chemosol product?

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A. There was no difference between the cigarettes that were treated with Chemosol and the reference which was the untreated cigarette. There was no difference in the number of tumors or frequency of tumors per mouse in the skin painting.

Q. Was it agreed at that time that the tobacco companies would not market a product based on the Chemosol formula?

A. No, there was no agreement about marketing. It was simply a sharing in the testing of the product consulting laboratory. As I say, we at Lorillard had been approached by these folks and conducted chemical tests on their claims and could not replicate or confirm their claims.

Q. In the last paragraph on the page, it indicates -- Mr. Wakeham indicates we believe that this testing should be done quietly and without fanfare. Do you know why Mr. Wakeham stated that we believe that the testing should be done quietly and without fanfare?

A. I don't know why Mr. Wakeham stated it. I know why I would feel that way.

Q. On the second page and last page, Mr. Wakeham says I suggest that we call a meeting of the technical representatives at some mutually convenient date for this purpose. Do you see that?

A. Yes, I do.

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Q. Do you know if the technical representatives met at some point after the date of this letter?

A. I don't recall.

Q. Was there a difference from the Chemosol project to the Hazleton protocol research proposal, if you turn back to page one -- I apologize for that. There are two points here, number one and two, the Hazleton protocol research proposal and the protocol for manufacture of Chemosol treated and control cigarettes. What was the difference between the two?

A. The Hazleton protocol was to carry out the mouse skin painting bioassay by smoking the cigarettes, collecting condensate and applying them to the animals, and the other protocol is to prepare or to have prepared cigarettes containing this invention called Chemosol and a reference -- so it's a protocol to manufacture cigarettes for that purpose.

Q. Do you know if Mr. Topol is a litigator?

A. Not to my knowledge.

Q. Do you know who Donald Hoel is, H-o-e-l?

A. Yes, I do.

Q. Can you tell me who Donald Hoel is?

A. He was an attorney with Shook, Hardy.

Q. Do you know if Mr. Hoel is still alive?

A. I believe so.

Q. Did you have any discussions with Mr. Finnegan?

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A. In the distant past, yes.

Q. Do you recall the last time you had any discussions with Mr. Finnegan?

A. No, it's been a very long time ago.

Q. Do you recall the nature of the subject matter of your discussion with Mr. Finnegan?

A. His firm represented the Council for Tobacco Research, and I would imagine that discussion was something surrounding the activities of the Council for Tobacco Research, but I have no recollection.

Q. Do you recall a gentleman by the name of Dr. Roger Bick?

A. Generally, yes.

Q. Do you recall what Dr. Bick did for the CTR?

A. I think he was on the advisory board, SAB.

Q. Do you know if CTR had to obtain the approval of the Committee of Counsel before making grants for research?

A. I'm sorry, would you repeat that?

Q. Do you know if the Committee of Counsel was -- whether the Committee of Counsel's prior approval was required by CTR before they made grants for specific research activities?

A. Not to my knowledge.

Q. Meaning that you don't know or that it wasn't a requirement?

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A. I think I would have known if that were a requirement, and I have no knowledge that that was a requirement. I think just the opposite, that the scientific advisory board made their decisions independently as to what would be funded.

Q. Do you know when it was first alleged that the application of diammonium phosphate to tobacco smoke had a significant affect on puff by puff smoke pH?

MR. ALLINDER: Object to the form.

THE WITNESS: I don't remember that specific allegation, no. I do recall Dr. Kessler's testimony at the Waxman hearing in which he stated that ammonium compounds, and he included this compound, were being used by the companies to modify the pH and the yield of nicotine.

BY MR. HEFTER:

Q. And do you recall when Dr. Kessler made these assertions?

A. At the Waxman hearing in 1994.

MR. HEFTER: I'm going to mark as Spears Exhibit No. 8 an internal memo number 4376, which is dated March 1, 1996 that purports to be from an R.T. Walker from an M.A. Sudholt.

(Exhibit No. 8 marked for identification.)

MR. ALLINDER: Is this one of the documents that's set forth in his expert report?

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MR. HEFTER: I believe it is, and that's my first question just to confirm.

The document I just marked as Spears Exhibit No. 8, Dr. Spears, is that the same document that is referenced on page four of Spears Exhibit No. 1 at the bottom.

THE WITNESS: It's one of the documents, yes.

BY MR. HEFTER:

Q. Right, and is that the document that's referred to as number three?

MR. ALLINDER: Why don't you find your expert report. There you are.

THE WITNESS: Yes.

BY MR. HEFTER:

Q. And this is one of the documents you are relying on in making your opinions that purport to be stated in Exhibit No. 1?

A. Yes.

Q. Who is R.T. Walker?

A. She was a chemist in our laboratory.

Q. She no longer work for Lorillard?

A. I don't know. I think she does, but I'm not sure.

Q. Who is M.A. Sudholt?

A. She is the head of our analytical research group.

Q. And currently the head of the analytical research group?

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A. Correct.

Q. Do you know who asked R.T. Walker to draft the report which is Exhibit No. 8?

A. Who asked her to draft the report, I do not, but it looks to be a routine laboratory report which was evaluating a substance that we use in our tobacco products.

Q. Let me ask you a different question. Did you ask Ms. Sudholt or Ms. Walker to prepare a report on the affect of diammonium phosphate on smoke pH?

A. I don't believe I asked for this particular report. I asked for one of the others, actually two of the others.

Q. And sitting here today you just don't know one way or the other who asked Ms. Walker or Ms. Sudholt to prepare this report?

A. I do not.

Q. And this document was prepared on or about March 1, 1996, is that correct?

A. That's the date on it.

MR. HEFTER: Let's mark the next Exhibit No. 9, internal memo number 4613.

(Exhibit No. 9 marked for identification.)

BY MR. HEFTER:

Q. Which is a memo from J.M. Johnson to M.A. Sudholt. Is this document referred to as document number one on page four of your expert report?

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A. Yes, it is.

Q. The date of this document is September 18, 1996, is that correct?

A. That's correct.

Q. Who is J.M. Johnson?

A. She is a chemist working under M.A. Sudholt.

Q. You had indicated that -- strike that.

Is it correct that you asked Mr. Johnson to prepare this report?

A. I asked that the study be undertaken. I don't think I asked Jennifer Johnson. I think I asked probably the director of research.

Q. Who at the time was --

A. Who at this time would have been I believe Bello Norman.

Q. The last name again?

A. Norman.

Q. Is that a man or a woman?

A. A man.

Q. And do you recall specifically having a discussion with Mr. Norman about preparation of a report regarding the affects of ammonium carbonate, ammonium bicarbonate, urea and diammonium phosphate on smoke pH, smoke data and pH chemistry?

A. I generally recall asking that we conduct a study

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with all of the agents that one might conceive of that would release ammonia into the smoke of cigarettes and see what impact, if any, they had on our measurement of pH and yield of nicotine.

Q. Do you recall when that discussion took place?

A. Sometime prior to this and sometime after the testimony at the Waxman hearing.

MR. HEFTER: Let me go ahead and mark Exhibit No. 10.

(Exhibit No. 10 marked for identification.)

BY MR. HEFTER:

Q. Which is for the record internal memo number 4524, a memo from J.M. Johnson to M.A. Sudholt, purports to be dated July 24, 1996. Is this the other report that you asked to be prepared?

A. Actually, I think this was prepared first and what you labeled as two is prepared second, and the first report which is number three was so complex in terms of its presentation of the data and analysis, that I asked that more of the summary report be prepared, which is the report that you referred to as report two.

Q. Did any subsequent research take place between the time that number one --

A. This is identical data in these two reports. It's just different presentation.

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Q. In your view did any conclusion change between the September 18th -- between the July 24th report and the September 18th report?

A. No, I don't believe there was any difference in opinion.

Q. But you asked -- who did you ask to have a -- I will use the term clearer -- that's not your testimony, I understand that, but clearer report to be prepared?

A. I think I asked Dr. Norman.

Q. Did you and Dr. Norman have any other discussion regarding the affects of these compounds at that period of time?

A. Other than what's in the report, no, I think the reports confirmed what I believed and probably he believed was the situation, it's quite different than what Dr. Kessler was asserting.

Q. Have you had any discussions with any representative of CNA regarding non-smoker premium differentials?

A. I do not believe so.

Q. Have you had any discussion regarding non-smoker premium differentials -- let me rephrase that.

Have you had any discussions with any person employed by The Tobacco Institute regarding insurance companies adopting non-smoker premium differentials?

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A. I have no recollection of any such conversation.

Q. Have you had any discussions with any employee, officer, director of any other tobacco company regarding insurance companies adopting non-premium smoker differentials?

A. No.

Q. Have you had any discussions regarding non-smoker premium differentials with any employee of Lorillard?

A. I don't recall any.

Q. Had have you had any discussions at any time with Mr. Stevens regarding insurance companies adopting non-premium smoker differentials?

A. I am aware I was copied on some letters, memos that Mr. Stevens wrote, but I have no specific recollection.

Q. And these memos this you are referring to, are these the ones you were shown yesterday?

A. That's correct.

Q. In your preparation session?

A. That's correct.

Q. And prior to yesterday, have you seen any of the documents that you were shown yesterday?

MR. ALLINDER: Object to the form.

THE WITNESS: I did not recall them.

BY MR. HEFTER:

Q. Have you ever been to a meeting of the AMA House of

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Delegates?

A. I do not believe so. I did go to a meeting of the medical research committee or something like that that I received a grant from the industry to conduct research.

Q. What was discussed at that meeting?

A. The results of some of the research grantees.

Q. Who else was in --

A. It was a scientific meeting.

Q. Were there medical doctors who are members of the AMA in attendance at that meeting?

A. I don't know whether they were members of the AMA or not.

Q. Were there medical doctors at the meeting?

A. I would think so, yes.

Q. Do you recall when that meeting took place?

A. I can't be sure, but I believe it was in the late '60s.

Q. Is that the only meeting you ever attended sponsored in whole or in part by the American Medical Association?

A. I believe that's true -- no, that's not true. I did go to other meetings. I have gone to other meetings where the AMA was a sponsor and these were research presentations.

Q. Do you recall when those meetings took place,

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generally?

A. No, I do not.

Q. Within the past ten years?

A. No.

Q. Were you a speaker at any of these meetings?

A. No.

Q. During your tenure at Lorillard, have you made speeches?

MR. ALLINDER: Objection to the form.

THE WITNESS: Yes, I have made speeches.

BY MR. HEFTER:

Q. Do you keep a file of the speeches that you have given?

A. There is a file. I don't know whether it's complete or not.

Q. Other than the research meetings that were sponsored in whole or in part by the AMA, can you think of any other meetings of the AMA that you have attended?

A. No, that's all I recall.

Q. Do you recall at any of these meetings that any industry representative made presentations?

A. No, I don't think so.

Q. At these meetings, researchers who received grants from the AMA had presented their research findings?

A. That's correct.

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Q. Other than yourself, were there any other industry representatives in attendance at those meetings?

A. I believe so, but it's so long ago I can't be specific.

Q. So you can't recall any of those people?

A. No, I don't recall.

Q. Do you recall if any industry representative criticized or commented adversely on any of the findings that were presented by any of the researchers who had received AMA grants?

MR. ALLINDER: Object to the form.

THE WITNESS: In the meeting?

BY MR. HEFTER:

Q. During these meetings.

MR. ALLINDER: Same objection.

THE WITNESS: I don't recall that, no.

MR. HEFTER: Give me one minute and I think I may be done.

(Recess was taken at 5:51 p.m. to 5:52 p.m.)

MR. HEFTER: I would just like to mark for the record Exhibit No. 11.

(Exhibit No. 11 marked for identification.)

MR. ALLINDER: Is it still your intention to complete your examination by 6:00 o'clock?

MR. HEFTER: Yes.

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MR. ALLINDER: I would like to note defendants' privilege objection for the record.

MR. HEFTER: It is noted for the record.

Have you had an opportunity to look at that document?

THE WITNESS: I haven't looked at the whole document. Okay, I have scanned it.

BY MR. HEFTER:

Q. I just have one question for you. Is that your handwriting that's reflected on the first page of the exhibit?

A. I don't believe so.

Q. Have you ever seen this document before?

A. I don't think so.

Q. I have a few more questions for you. With respect to the working group of The Tobacco Institute, did you -- were minutes of your meetings distributed to you?

MR. ALLINDER: Object to the form.

THE WITNESS: As I recall, the meetings were recorded and there was a summary, I guess, of the tapes prepared for the members in terms of the significant, what were thought to be the significant points at the meeting.

BY MR. HEFTER:

Q. Did you receive --

A. I think I received these reports, yes.

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Q. And in a written format?

A. Yes, but they were not minutes of the meeting. They were -- one of the people's summary of what transpired at the meeting.

Q. And did the tobacco industry representatives have an opportunity to change in any way the summary?

A. No.

Q. Do you recall ever personally making any changes to the summaries to the tobacco working group's summary that was prepared?

A. No, I don't think there was much attention paid to those summaries quite frankly. The activity as a group were results in terms of reports and data presentations.

MR. HEFTER: I don't have any further questions for the witness at this time.

MR. ALLINDER: Do you intend to examine him, Brian?

MR. BROWN: Excuse me, I do for a brief amount of time.

MR. ALLINDER: What is the brief amount of time that you expect you would be asking questions?

MR. BROWN: Depending on the answers, no more than ten to 15 minutes.

MR. ALLINDER: Let's take a brief break.

(Recess was taken from 5:55 p.m. to 6:00 p.m.)

EXAMINATION BY COUNSEL FOR PLAINTIFFS

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THE NATIONAL ASBESTOS WORKERS MEDICAL FUND ET AL.

BY MR. BROWN:

Q. Good afternoon, Dr. Spears. I introduced myself earlier, but I will introduce myself on the record. My name is Brian Brown, and I represent the plaintiffs in the National Asbestos Workers case that's filed in the Federal District Court of New York.

Have you reviewed the complaint in that case, sir?

A. Yes, I have.

Q. When did you review the complaint in that case?

A. I reviewed it yesterday.

Q. Sir, I would like you to look at what's been pre-marked as Spears Exhibit No. 12, that's the expert disclosure that's been filed in this case on your own behalf. I'm going to ask you to briefly compare that to Spears Exhibit No. 1, which is the expert disclosure offered in the BlueCross And BlueShield of New Jersey case, and to save time, my question to you is going to be are they substantially similar in form and substance?

A. In my opinion they are.

Q. Sir, you have offered testimony today in the BlueCross of New Jersey case, is that correct?

A. That's correct.

Q. And would any of that testimony that you have offered today change in the National Asbestos Workers case if

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offered in that case?

A. No, it would not.

Q. Would there be any additions to the testimony that you have offered today in the National Asbestos Workers case that you haven't offered in the BlueCross of New Jersey case?

MR. ALLINDER: Object to the form.

THE WITNESS: Only if I were asked different questions, it may change in response to those questions.

BY MR. BROWN:

Q. And, Dr. Spears, you testified earlier today that beginning and I don't want to mischaracterize your testimony, so correct me if I'm wrong, but beginning at the beginning of this year, January of 2000, you reviewed to date about 100 articles, is that correct?

A. That was an estimate that I made when asked how many articles might I have reviewed in that period.

Q. And you gave us examples of the types of articles you reviewed, is that correct?

A. I gave some examples, yes.

Q. And some of those examples would be articles related to asbestos and smoking, is that correct?

A. I mentioned some of those, yes.

Q. And a summary of fiber and carcinogenesis, is that correct?

A. Yes, I mentioned that.

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Q. Do you intend to offer an opinion in the National Asbestos Workers case regarding any information that you gleaned from the review of these 100 articles, approximately 100 articles?

A. Again, it depends on what questions I'm asked regarding asbestos and malignancies.

Q. And what is your opinion regarding asbestos and malignancies?

A. My first opinion is that asbestos is a carcinogenic agent, that there is human data in terms of epidemiology. There is also animal data by the inhalation model and there have been mechanistic studies on potential mechanisms by which asbestos creates the effects of the tumorigenesis.

Q. Any other opinions that you would offer at trial regarding the relationship between asbestos and smoking?

A. Between asbestos and smoking, I would have opinions on the subject of synergy, and I guess first you need a definition of synergy and basically talking about a multiplicative affect in terms of lung tumor and I think the evidence is not supportive of the multiplicative effect, and I believe that is summarized in my judgment in a paper by Aaron in, I think, epidemiology published in 1999, a rather recent paper.

My interpretation of that paper which is a summary of a battery of epidemiological studies is that it's not

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supportive of synergy as I have defined it.

Q. What forms the basis of your opinion regarding synergy other than the Aaron article which you just mentioned?

A. The Aaron article is a statistical analysis of the various studies and a summary of those statistics or I think it's 12 studies.

Q. Do you intend to rely on any of the hundred articles that you reviewed since January of 2000?

A. In what respect?

Q. In offering expert testimony in the National Asbestos Workers case?

A. I think I would, yes.

Q. Can you look at Spears Exhibit No. 12, please, and can you tell me if there is an expert opinion contained regarding asbestos and smoking in your expert disclosure?

A. I don't believe it specifically mentions asbestos, no.

MR. BROWN: And, Bill, for the record, we would request these 100 articles that he has reviewed since January of 2000 if he intends to rely on them to formulate the opinions in this case.

MR. ALLINDER: The request is noted.

MR. BROWN: We also reserve the right to continue the deposition on the basis of these 100 articles if we deem

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proper.

MR. ALLINDER: So noted.

THE WITNESS: Can I say something?

MR. ALLINDER: No, sir. Do you need to clarify a former testimony?

THE WITNESS: Yes. I don't think I said 100 articles on asbestos. I think that was in response to a question of how many articles had I reviewed on the subject of smoking and health.

BY MR. BROWN:

Q. Well, I would request any articles which Dr. Spears intends to rely upon to formulate the opinions which he will offer at trial in this matter.

MR. ALLINDER: I understood that to be your request.

MR. BROWN: Thank you.

Earlier today, Dr. Spears, you testified about three definitions of addiction. One of them was what you deemed a public definition and the other were two scientific definitions of addiction. Do you recall that testimony?

THE WITNESS: I do.

BY MR. BROWN:

Q. And one of the scientific definitions was based on the DSM IV, is that correct?

A. That's correct.

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Q. And when was the DSM IV published?
A. Probably about ten years ago.
Q. So that would be about 1990?
A. 1990 or thereabouts.
Q. And so I don't mischaracterize your testimony earlier, do you believe that nicotine is addictive under the DSM IV definition of addiction?
A. As I recall -- as I recall that, I don't think addiction is used. The term dependence is used, so you must equate dependence with addiction to call it addiction. If you want to make that equation or that equivalency, then you can call it addiction, but I don't believe the diagnostic statistical manual specifically defines addiction. It defines dependence.
The Surgeon General's report which I think I said in the early '80s I believe is now the late '80s does make that reference to that definition and call it addiction. They make the leap from dependence to addiction.
Q. When did you first see the DSM IV definition of dependence?
A. I think shortly after it appeared.
Q. And correct me if I'm wrong, but earlier did you testify that you spoke to Mr. Tisch prior to his testimony in front of Congress in 1994?
MR. ALLINDER: Object to the form.

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THE WITNESS: Yes, I think I spoke to Mr. Tisch, yes.

BY MR. BROWN:

Q. And what did you talk to Mr. Tisch about prior to his testimony?

A. I think I reviewed his written testimony or proposed written testimony at the time, I guess.

Q. What was the discussion about?

A. I don't recall specifically, but the accuracy of his testimony, scientific accuracy of his testimony.

Q. Did you discuss the fact of whether Lorillard believed nicotine was addictive or not?

A. I don't recall that. I don't think that was part of his written testimony.

Q. Did you ever discuss that with him prior to his testimony in 1994?

A. I don't remember.

Q. You don't remember one way or the other?

A. I don't remember one way or the other.

Q. If I can direct your attention to Spears Exhibit No. 12, which is your expert disclosure, to page -- bottom of page three, the last paragraph there, last sentence. It reads I may also testify that the statistical associations upon which cigarette smoke has been reported to be a risk factor for human diseases do not themselves establish proof

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of causation in a scientific sense.

Did I read that correctly?

A. You did.

Q. What expert opinion do you believe that you will offer from that statement?

A. I will offer that particular belief and support it with the fact that there have been epidemiological studies on other subjects that have had confounders that have altered the risk and misrepresented the risk and generally the observation that this is a statistical correlation. It is not a way to prove causation. It appears in the literature generally that this is not the -- you cannot prove causation by epidemiological evidence alone unless that evidence -- unless there is a short term -- short time term between exposure and the disease, and that is not true of the chronic diseases that we are talking about with respect to association with cigarette smoke.

Cancer, heart disease are all diseases of the elderly by and large, and I think it's an accurate statement to say scientifically you cannot prove causation by simply a statistical association with these kind of diseases because there are too many opportunities for bias and confounding.

Q. Can you tell me any specific support for the statement that I just read into the record?

MR. ALLINDER: Object to the form.

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THE WITNESS: Are you asking for references?

BY MR. BROWN:

Q. Yes.

A. I can't cite them just offhand, but certainly the earlier Surgeon General's reports made that assertion, what they believe was necessary to show causation, which was, first of all, epidemiological evidence, the strength of the association, the temporal relationship between exposure and the disease, biological plausibility, which goes beyond now epidemiology.

These are all laid out I think in the first Surgeon General's report as one quick reference I can give you, but there are articles in the literature that discuss this.

Q. Do you know the names of any of those articles right now sitting here?

MR. ALLINDER: Object to the form.

THE WITNESS: I can't give them to you, but there is no question in my mind that they exist and there are plenty of them.

MR. BROWN: I have no further questions at this time.

MR. ALLINDER: Before we go off the record, I want to inform the court reporters that this deposition transcript will be designated as being subject to the protective order in this case and should you need information as to how to

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make that designation in the record, please call me or get in contact with me.

I have no questions for Dr. Spears.

(Signature reserved.)

(Whereupon, at 6:15 p.m., the taking of the instant deposition ceased.)

_____

Signature of the Witness

SUBSCRIBED and SWORN TO before me this _____

day of _____, 20____.

_____

NOTARY PUBLIC

My Commission expires: _____

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E R R A T A S H E E T

RE: BLUE CROSS AND BLUE SHIELD OF NEW JERSEY, ET AL., V. PHILIP MORRIS, INCORPORATED, ET AL.

DEPOSITION OF: ALEXANDER W. SPEARS, III, Ph.D.

Please read this original deposition with care, and if you find any corrections or changes you wish made, list them by page and line number below. DO NOT WRITE IN THE DEPOSITION ITSELF. Return the deposition to this office after it is signed. We would appreciate your prompt attention to this matter.

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CERTIFICATE OF REPORTER

STATE OF NORTH CAROLINA)

COUNTY OF MECKLENURG)

I, Andrea L. Nobrega, the officer before whom the foregoing deposition was taken, do hereby certify that the witness whose testimony appears in the foregoing deposition was duly sworn by me; that the testimony of said witness was taken by me to the best of my ability and thereafter reduced to typewriting under my direction; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this deposition was taken, and further that I am not a relative or employee of any attorney or counsel employed by the parties thereto, nor financially or otherwise interested in the outcome of the action.

Andrea L. Nobrega

ANDREA L. NOBREGA
Court Reporter and Notary
Public in and for
North Carolina.

My commission expires: 11-25-01

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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

BLUE CROSS AND BLUE SHIELD OF NEW JERSEY, et al., Plaintiffs, vs. PHILIP MORRIS, INCORPORATED, et al., Defendants.	)	98 Civ. 3287 (JBW)

EXPERT REPORT OF DR. ALEXANDER WHITE SPEARS III

BACKGROUND AND QUALIFICATIONS:

I am the Chairman of the Board of Lorillard Tobacco Company. I have worked for Lorillard Tobacco Company and related entities (collectively "Lorillard") from 1959 to the present. I graduated from Allegheny College in 1953 (B.S.) and received my Ph.D. in chemistry from the State University of New York in Buffalo in 1960.

In addition to my current positions with Lorillard, I have served in the following positions at Lorillard since 1959: Research Associate (1959), Senior Research Chemist, Greensboro Division (1961-65), Director, Basic Research (1965-68), Vice President, Research and Development (1971-75), Senior Vice President, Operations and Research (1975-79), Executive Vice President, Operations and Research (1979-1991), Vice Chairman and Chief Operating Officer (1991-95), and Chief Executive Officer (1995-98). I have also served as an instructor of chemistry at Millard

PLAINTIFF'S EXHIBIT 1 Dr. Spears

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Fillmore College from 1958 to 1959 and as an Assistant Professor of Chemistry at Guilford College from 1961 to 1965.

I am currently a member of the American Chemical Society, the American Association for Advancement of Science, the Society for Applied Spectroscopy, and the New York Academy of Science. I have served on the Editorial Board of Tobacco Science Journal from 1966 to 1969; as an advisor to the National Cancer Institute from 1968 to the late 1970s; a Member of the Scientific Commission of CORESTA from 1972 to 1976; a member of the U.S. Technical Study Group, Cigarette Safety Act of 1984 from 1984 to 1987; a member of the U.S. CPSC Technical Advisory Group, Fire Safe Cigarette Act of 1990 from 1990 to 1993; Chairman of the Board of Directors for the Center for Indoor Air Research from 1991 to 1995 (and a member from 1988 to the present); and was a member of the Board of Directors for the Council for Tobacco Research-U.S.A., Inc. from 1990 to the present.

I have also contributed research in the areas of pyrolytic reactions and products, spectroscopy, chromatography, analytical methods, structure of natural products, and tobacco and foods.

SUMMARY OF OPINIONS

I am being listed as a fact and expert witness in this matter. This report sets forth the expert testimony that I may offer at trial. I am expected to give testimony regarding the research, design, testing and manufacture of Lorillard cigarettes during the relevant time period.

I may testify about Lorillard's historical awareness of reports regarding the relationship between smoking and health and the actions Lorillard took in response to those reports,

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including Lorillard's cooperation with Dr. Wynder's research attempts to determine the relationship between cigarette "tar" and lung cancer. I may also testify about the scientific methodology used from time to time in the research relating to smoking and health issues, including mouse skin painting and animal smoke inhalation studies.

I may testify about research Lorillard has sponsored or conducted in-house on smoking and health issues, including research relating to the chemical composition of cigarette smoke. I may also testify concerning Lorillard's efforts to reduce selected components of smoke over time and other historical research efforts, including Lorillard's and others' research in the areas of benzo(a)pyrene, phenols, ciliastasis, and lung clearance mechanisms.[5]

I may testify on the subject of cigarette design and the reduction in "tar" and nicotine levels in cigarettes in the past several decades. I may testify that, in designing cigarettes, Lorillard has responded to scientific and public health concerns and to smokers' demands. I may also testify concerning Lorillard's efforts to modify its products over the years.

I may testify about my experience as technical adviser to the National Cancer Institute's Tobacco Working Group from 1968 to the late 1970s and offer my expert opinion on the results of research sponsored and reviewed under its auspices. I may testify that Lorillard and other members of the tobacco industry cooperated with and shared research ideas and results with the National Cancer Institute's Tobacco Working Group.

I also may testify about the opinions and basis thereof expressed by the plaintiffs' witnesses relating to cigarette design and manufacture, including any allegations pertaining to "smoker compensation," nicotine "manipulation," "spiking," reconstituted tobacco, ph, ammonia

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and additives, allegations about Lorillard research and development efforts, and allegations about company research on so-called "safer cigarette."

I may be asked to comment on the opinions expressed by other witnesses in this case and the evidence on which they rely, to the extent such evidence or opinions are within the scope of my expertise.

My expected testimony and opinions may be based upon my education, training, teaching, research, personal experience and expertise, my review of pertinent scientific information and literature, other information reasonably relied on by members of the profession, and my review of information, testimony, and documents concerning this case. I may also rely on documents and materials used by or relevant to the issues raised by plaintiffs' expert witnesses. Included in my Curriculum Vitae, a copy of which is attached hereto as Exhibit A, is a list of my publications upon which I may also rely. In addition to the materials and information described herein, I may also base my testimony on the following internal Lorillard documents:

1. Summary of the Effects of Ammonium Carbonate, Ammonium Bicarbonate, Urea and Diammonium Phosphate on Smoke PH, Smoke Data and Leaf Chemistry;
2. Statistical Evaluations of the Effects of Ammonium Carbonate, Ammonium Bicarbonate, Urea and Diammonium Phosphate on Smoke PH, Smoke Data and Leaf Chemistry; and
3. The Effect of Diammonium Phosphate (DAP) on Smoke PH and Nicotine Delivery.

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The materials upon which I rely are either publicly available or have been produced into the Minnesota Document Depository. I will not be separately compensated for my services as an expert in this action.

Alexander W. Spears III

Dr. Alexander W. Spears III

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ALEXANDER WHITE SPEARS III

Chairman
Lorillard Tobacco Company
714 Green Valley Road, Greensboro, NC 27408

Residence: [DELETED]

Place of Birth: Grindstone, PA ([DELETED] 1932)

Parents: A. W. Spears, M.D. (dec.) and Eva Elliott Spears (dec.)

Education: B.S. Allegheny College, 1953
Ph.D. State University of NY at Buffalo, 1960

Married: Shirley Spears

Children: Craig Stewart Spears

Service Record: U.S. Army, 1953-55

Experience: Research Associate, State University of NY at Buffalo, 1956-58

Research Fellow, ibid., 1958-59

Instructor, Millard Fillmore College, 1958-59

Research Associate, P. Lorillard Company, 1959-61

Assistant Professor, Guilford College, 1961-65

Senior Research Chemist, Greensboro Division, P. Lorillard Company, 1961-65

Director, Basic Research, P. Lorillard Company, 1965-68

Director, Research and Development, Lorillard, A Division of Loews Theatres, Inc., 1968-71

Vice President, Research and Development, Lorillard, A Division of Loews Theatres, Inc., 1971-75

Senior Vice President, Operations and Research, Lorillard, A Division of Loews Theatres, Inc., 1975-79

Executive Vice President, Operations and Research, Lorillard, A Division of Loews Theatres, Inc., 1979-85, Lorillard, Inc., 1985-89, Lorillard Tobacco Company, 1989-91.

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Vice Chairman and Chief Operating Officer, Lorillard Tobacco Company, 1991-95.

Chairman and Chief Executive Officer, Lorillard Tobacco Company, 1995-99.

Chairman, Lorillard Tobacco Company, 1999 to present.

Lorillard, Inc., Board of Directors, Chairman, 1995-1999.

Lorillard Tobacco Company, Board of Directors, Chairman, 1995 to present.

Professional Memberships and Honors:

American Chemical Society; Society for Applied Spectroscopy; New York Academy of Science; Sigma Xi; American Association for the Advancement of Science; Who's Who in America; Who's Who in Finance and Industry; Who's Who in Science and Engineering. Distinguished Achievement Award in Tobacco Science, Philip Morris, 1970. Honorary Chairman, 1994 Kmart-Greater Greensboro Open. 1994 Junior Achievement Business Leaders Hall of Fame. 1994 YMCA Hall of Fame. YMCA Honorary Life Member, 1996 - . Honorary Appointment to American Judicature Society, 1998. Guest speaker at the Tobacco Merchants Association 84th Annual Dinner Meeting, 1999. 1999 National Brotherhood Award by the National Conference for Community and Justice.

Related Activities:

Editorial Board, Tobacco Science Journal, 1966-69; Advisor, National Cancer Institute, 1968-78; Member, Scientific Commission of CORESTA, 1972-76; Testimony before the Federal Trade Commission regarding development of method for tar and nicotine determination, 1966; Testimony before the U.S. Senate Subcommittee on Health and the Environment of the Committee on Energy and Commerce for Its Hearing on H.F. 1880, 1983; Testimony before the New York Legislature Senate Finance Subcommittee on Fire Safety and Assembly Subcommittee on Volunteer Firemen, 1984. Member, U.S. Technical Study Group, Cigarette Safety Act of 1984 -- 1984-87, and of the U.S. CPSC-Technical Advisory Group, Fire Safe Cigarette Act of 1990 -- 1990-93. Chairman, Board of Directors, Center for Indoor Air Research, 1991-95 (member, 1988 to present); Member, Board of Directors, The Council for Tobacco Research-U.S.A., Inc., 1990-99.

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Testimony before the Subcommittee on Commerce, Consumer Protection and Competitiveness regarding fire-safe cigarettes HR 293 and HR 673, 1990.

Areas of Research: Pyrolytic Reactions and Products; Spectroscopy; Chromatography; Analytical Methods: Structure of Natural Products; Tobacco; Foods.

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Community Activities:

Board of Directors, Greensboro Chamber of Commerce, 1974 & 1975, 1986 & 1987, 1996-99 , Chairman, 1997. Member, Greensboro Community Initiative, 1996- . Chairman, Council on Education, 1974. Nathaniel Greene Award, 1975. Executive Committee, 1987, 1997.

Chairman, Model School Task Force, jointly sponsored by the Board of Education of the Greensboro Public Schools and the Greensboro Chamber of Commerce, 1975.

Board of Directors, United Way of Greensboro, 1980-85; 1997-99. Cabinet Chairman, United Way of Greensboro, 1999. Campaign Chairman, United Way of Greater Greensboro, 1999.

Member, North Carolina Humanities Committee, 1978-81.

General Chairman, Bennett College/United Negro College Fund, 1982 Campaign.

Member, The Governor's Business Committee for Math & Science Education, 1983-84.

Board of Directors, North Carolina Citizens for Business and Industry, 1984-88.

Chairman, Greensboro Public School Fund, 1987.

Greensboro Area Chairman, Triad Girl Scouts Capital Campaign, 1987.

Board of Directors, N.C. A & T University Foundation, 1985-93. Board of Trustees, 1990 - ; Secretary, 1995-97, Vice Chairman, 1997-99; General Chairman, "Focus on Excellence" Fund-Raising Campaign, 1984-86.

Board of Directors, Greensboro National Bank, 1980-91; Vice Chairman,1989; Executive Committee, 1987-91.

General Chairman, Greensboro Historical Museum Capital Campaign, 1988, 1989; Board of Trustees, 1989 - .

Business Advisory Board of University of North Carolina at Greensboro, Joseph M. Bryan School of Business & Economics, 1988-94.

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Board of Directors, Greensboro Development Corporation, 1985 - ; President, 1992-94; Executive Committee, 1987-; Economic Development Committee, 1991-94; Forward Guilford II Executive Committee, 1998 - .

Board of Directors, Greensboro Metro YMCA, 1989-96; Chairman, 1993-95; Executive Committee, 1991-97; Chairman, Hayes-Taylor Capital Campaign 1990. YMCA Hall of Fame, 1994. YMCA Honorary Life Member, 1996 - .

Board of Visitors-Chairman, Greensboro College, 1990-95.

Board of Trustees, Guilford College, 1995 - ; Board of Visitors, 1990, 1991.

Board of Directors, National Conference of Community and Justice (a.k.a. National Conference of Christians and Jews), 1990-92; Chairman, 1991 NCCJ Annual Brotherhood Citation Dinner, Greensboro Chapter. 1999 National Brotherhood Award by the NCCJ.

Piedmont Triad Airport Authority, member, 1993 - ; Treasurer, 1995-97; Vice Chair, 1997-99.

Advisory Council, North Carolina Center for Nonprofits, 1999 -.

Member, Greensboro Sports Council.

Member, Rotary Clubs of Greensboro.

Member, First Presbyterian Church, Greensboro, NC.

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"The Synthesis of Some 2,4,5-Trisubstituted Pyrimidines." Journal of Organic Chemistry, 25:2137 (1960). Peters, E., Minnemeyer, H.J., Spears, A.W., and Tieckelmann, H.

"The Synthesis of Phthaloyltauryl Peptides." Journal of Organic Chemistry, 26:1498 (1961). Spears, A.W. and Tieckelmann, H.

"The Determination of Saturated Hydrocarbons in Cigarette Smoke Condensate." 16th Tobacco Chemists' Research Conference, 1962. Spears, A.W., Lassiter, C.W., and Bell, J.H.

"Quantitative Determination of Alkanes in Cigarette Smoke." Journal of Chromatography, 34 (1963). Spears, A.W., Lassiter, C.W., and Bell, J.H.

"Quantitative Determination of Phenol in Cigarette Smoke." Analytical Chemistry, 35:320 (1963). Spears, A.W.

"Selective Filtration of Volatile Phenolic Compounds from Cigarette Smoke." Tobacco Science, 7:76 (1963). Spears, A.W.

"A Combined Approach to the Quantitative Analyses of the Volatile Components of Cigarette Smoke." 18th Tobacco Chemists' Research Conference, October 20-22, 1964, Raleigh, NC. Spears, A.W. and Routh, W.E.

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"Determination of Moisture in Total Particulate Matter." Tobacco Science, 10:75 (1966). Schultz, F.J. and Spears, A.W.

"The Contributions of Tobacco Constituents to Phenol Yield of Cigarettes." Tobacco Science, 10:138 (1966). Bell, J.W., Saunders, A.O., and Spears, A.W.

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"Difference in Ciliotoxicity of Cigarette Smoke. Comparison of Two Exposure Methods. "American Review of Respiratory Disease, 96:1078 (1967). Dalhamn, T., Rylander, R., and Spears, A.W.

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"A Convenient Synthesis of the True 6,7-Acechrysene." Journal of Organic Chemistry, 34: 1176 (1969). Lewis, C.I., Chang, J.Y., and Spears, A.W.

"Identification of Alkylated Phenanthrenes in Cigarette Smoke Condensate." 23rd Tobacco Chemists' Research Conference, 1969. Bell, J.H., Ireland, M.S., Schultz, F.J., and Spears, A.W.

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"Preliminary Studies of Substituted Phenanthrene Preparation via Photocyclization of Stilbenes and Butadienes." 23rd Tobacco Chemists' Research Conference, 1969. Lewis, C.I., Chang, J.Y., Schultz, F.J., and Spears, A.W.

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"Factors Affecting Smoke Delivery of Nicotine and Carbon Monoxide." Published in 1975 Symposium, Nicotine and Carbon Monoxide, presented by the Tobacco and Health Research Board, Nov. 17-18, 1975, University of Kentucky, Lexington, KY. Spears, A.W.

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DEPOSITION AND TRIAL TESTIMONY OF ALEXANDER W. SPEARS III NOVEMBER, 1995 - PRESENT		
DATE	**TYPE OF TESTIMONY**	**CASE**
November 16, 1995 November 22, 1995	Trial Testimony	Braun
December 13, 1995	Deposition Testimony	Roth
January 17, 1996	Deposition Testimony	Roth
February 26, 1996 February 28, 1996	Trial Testimony	Roth
March 8, 1996	Trial Testimony	Newman
March 18, 1996	Trial Testimony	Roth
April 17 - 18, 1996	Trial Testimony	Lesnick
August 13 - 14, 1996	Deposition Testimony	Florida - AG
April 15, 1997	Deposition Testimony	Broin & Engle
June 10 - 11, 1997	Deposition Testimony	Sorise
June 12, 1997	Trial Testimony	Sorise
July 24 - 25, 1997	Deposition Testimony	Barnes; Frosina; Hoberman; Hoskins; Small; Florida - AG; Texas - AG; Zito
August 8, 1997 August 18 - 19, 1997	Trial Testimony	Broin
September 23 -25, 1997	Deposition Testimony	Minnesota - AG
March 3, 1998	Trial Testimony	Dunn
June 24, 1998	Deposition Testimony	Washington -AG
September 25, 1998	Deposition Testimony	Minnesota - AG
January 25, 1999	Trial Testimony	Engle
March 17 - 18, 1999	Trial Testimony	Engle
March 5, 1999	Deposition Testimony	Butler
May 19, 1999	Trial Testimony	Butler

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PLAINTIFF'S EXHIBIT
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Dr. Spears

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DEPOSITION AND TRIAL TESTIMONY OF ALEXANDER W. SPEARS III NOVEMBER, 1995 - PRESENT		
DATE	**TYPE OF TESTIMONY**	**CASE**
June 16, 1999	Deposition Testimony	*NY Individual Actions*: Anderson; Brand; Evans; Gruder; Guilloteau; Hellen; Iacono; Knutsen; Krochtengel; Leiderman; Litke; Lucca; Maisonet; Perez; Piccione; Reitano; Rinaldi; Schwartz; Siegel; Sprung; Wagner;

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Citation
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2000 WL 2289055
(Publication page references are not available for this document.)

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Sunday, March 5, 2000

Outlook

PLAINTIFF'S EXHIBIT 3 Dr Speers

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Verbatim; Big Tobacco's Changing Tune

Big Tobacco is reeling from lawsuits (the latest is by the Canadian province of Ontario over the cost of smokers' health care) and waiting for a U.S. Supreme Court ruling on whether the industry will be regulated by the Food and Drug Administration. Against this backdrop, tobacco companies are fighting to improve their public image, and none is trying harder than industry giant Philip Morris (Marlboro, Virginia Slims). Appearing on a panel at a substance abuse conference in California last week, Philip Morris senior vice president Steven Parrish sparred with former FDA commissioner David Kessler--making statements that went well beyond anything his fellow cigarette makers have said, such as an admission that nicotine is an addictive drug.

Anti-tobacco activists see Parrish's statements as little more than public relations maneuvers, but even skeptics were struck by some of his words. Following are edited excerpts from the panel discussion, taken from a transcript provided by Kessler's staff. The excerpts begin as the moderator, television journalist Sander Vanocur, noted Parrish's statement earlier in the week that "Philip Morris is open to some regulation" by the FDA.

VANOCUR: . . . Is this a genuine epiphany?

PARRISH: It is an honestly held, good-faith belief on my part that there needs to be more than just some regulation. . . . There needs to be serious regulation of the tobacco industry at the federal level. The way I get there is much the same way that Dr. Kessler gets there when he talked to the Congress of the United States a couple of years ago, when he said, here we have a dangerous product, tobacco, which is addictive, which causes harm to some of the people who use it . . .

VANOCUR: What is the motive [for Parrish's concession], Dr. Kessler?

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KESSLER: I don't know. I'd like to believe that this is a first step. . . . Everyone is wondering whether they can believe it. You know well that for the last 50 years the industry has been engaged in some of the greatest deceptions ever on the public health. . . . I think there is one fundamental question, one very important question, this is where I start: Is nicotine a drug?

PARRISH: I believe that nicotine is a drug. I do not believe . . . that merely because nicotine is a drug that that means it should be regulated as a pharmaceutical or as a medical device under the Food, Drug and Cosmetic Act. That is the subject of the Supreme Court case [Food and Drug Administration v. Brown and Williamson Tobacco Corp.] and that will be resolved one way or another. But I don't think this should stop us--the fact that there is this very fundamental dispute about the proposed FDA rule--in trying to talk about what is the right way to regulate the product so that when the Supreme Court rules, no matter what the outcome is, we are better prepared to move forward.

. . . Here is one of my fundamental points: As I understand what government lawyers said in the Supreme Court case, if the FDA regulates tobacco as a medical device, which is what the proposal is, that it is subject to the safety and efficacy requirements of the act [therefore, either on its own or pursuant to a petition by a third party, FDA could be forced to ban the product to adults. I don't think that makes sense. . . . So I want to sit down and talk to you, obviously, and a lot of other people about what is the right regulatory regime for tobacco, not as a pharmaceutical or as a medical device but as a tobacco product--which is addictive, I've conceded that, and which causes harm to some people.

KESSLER: But [you have] no problem saying that it is an addictive drug?

PARRISH: I have no problem saying that. I don't think it is a drug as that is defined by the act, but I do think nicotine is a drug. I mean it is listed in the [U.S.] Pharmacopeia. . . . I don't want to quibble here. . . . I believe the federal government should regulate tobacco. I have some ideas that I think we can agree on . . . like how do we develop safer products, less addictive products, how do we keep the product out of the hands of kids? . . .

KESSLER: The reality is, if we don't sell tobacco, young people don't start. Do you agree with the goal, not having young people smoke?

PARRISH: I do.

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KESSLER: If we achieve that goal then the fact is, you don't start then, you know what that means to your industry?

PARRISH: I believe that in the future there will be a smaller group of people who smoke, but, if you are right, Dr. Kessler, and [if] as a result of cracking down and doing everything we can in a comprehensive way to keep kids from smoking our adult business dries up, our company is prepared to accept that. And I know that doesn't make sense to a lot of people but I can tell you, having lived through this for the last six years, that our belief is, if we are perceived to be a part of the smoking problem, then society in this country will not allow our corporation to exist. We have one of the finest companies in the world, we own Kraft Food, Miller Brewing and lot of other great businesses. We want those businesses to continue growing. But if we are not part of the solution I think the future of our company is not a good one. That's why, if no adults smoke as a result of cracking down on youth smoking, we are prepared to accept that and we will invest our assets in other businesses.

KESSLER: But those are generalities. The question is, are you willing to accept meaningful and real FDA regulation?

PARRISH: Yes.

KESSLER: The rule that FDA promulgated had two essential pieces: restrictions on access, making it harder for young people to buy, eliminating vending machines; [and] reducing the appeal, reducing the advertising and promotion directed at young people. Anything wrong with anything in that rule?

PARRISH: I don't think there's anything wrong with those approaches. I have a question about what's the appropriate role of FDA in some of those steps . . . What I want to talk about is what is the right way to regulate the product going forward. That is the topic of our panel. Let's work together to figure out the regulatory system, talking to members of Congress, that makes sense for tobacco products. I understand the skepticism, I understand the hostility. We have spent so much time pointing fingers at one another. . . . That is over as far as I am concerned, for my part that is not going to happen. What I want to do is figure out a policy that makes sense for the future, for one of the products that my company makes. . . .

---- INDEX REFERENCES ----

COMPANY (TICKER): Philip Morris Cos. (MO)

KEY WORDS: OUTLOOK

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Philip Morris Exhibit

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NEWS SUBJECT: Washington Post; Editorials and Columns; World Equity Index; Editorial Page; General News (WP EDC WEI EDI GEN)

NEWS CATEGORY: NEWS NATIONAL;TRANSCRIPT

INDUSTRY: Tobacco; Food Producers, Excluding Fishing; Food Products (TOB OFP FOD)

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COUNCIL FOR TOBACCO RESEARCH

American and other companies dismayed at direction of CTR research. (Heimann letter) opposed to contract research. American (and apparently others) convinced that Gardner and Kreisher are committed to attempting to demonstrate how tobacco smoke causes disease, rather than whether it causes disease (Yeaman disputes this impression).

Question whether CTR can be said to be independent when it is conducting its own proposed research, through contracts, rather than through grants.

Should SAB be advisory - or should it "run the show" with the Scientific Director as a mere administrator.

In January 1977 there was thought to be an agreement (C/C) that promotive carcinogenic experiments were not to proceed until whole smoke work completed. Apparently that work went forward anyway (at Gardner's direction or as a result of misunderstanding).

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AREAS OF PRESENT CONCERN EXPRESSED BY COMPANIES - REVIEWED BY YEAMAN WITH GARDNER - CURRENT STATUS

1. Loading of smoke/implantation into animal trachea of methyl colantherine (not found in tobacco smoke). Companies would have preferred that the work be deferred until whole smoke inhalation work completed.

   - Work is in progress. Yeaman "hopeful" it will not be extended or further developed.

2. AAH (aryl hydrocarbon hydroxylases) - marker for susceptibility to cancer. Catalytic effect on benzopyrene. Proposed seminar and publication of papers. Should more significant results be achieved before such activities went forward.

   - Meeting plans were too far advanced to scrap. Meeting was held. Publication will be postponed.

3. Effect of nicotine on Central Nervous System. Going beyond health mandate of CTR? Does this involve commercial/competitive aspects (substitutes - blocks - for nicotine). P-M visit to Abood. Abood presentation to Lorillard. Relationship to FTC subpoena.

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- Rationale by Ford prepared. May have commercial implications which could/should be avoided by CTR. Unresolved.

4. Dissatisfaction with views held by Kreisher. Contemptuous/insubordinate. Should be separated.

- Gardner receptive. Will be accomplished in time.

Impressions regarding staff re lack of scientific objectivity - possible bias against Industry.

Considerations of inherent risks in smoking/health research.

Does Industry still want/need independent, objective SAB and Staff.

<u>YEAMAN STATEMENT AT BOCA RATON</u>

The Industry must face clearly the question whether it is best served by continuing CTR under its present Commission, i.e., to investigate the relation of smoking to health, free of direction or control by the Industry. You cannot have it both ways. Cannot tell the Scientific Director and the SAB "here is your money, spend it in

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your best judgment" - and, at the same time say - "but don't go into the question of _____."

Gardner contends that some of these difficult questions must be answered piece-meal - thereby creating some problem areas of examination.

Do we want a CTR?

Are we prepared to phase it out?

Should the Staff be changed, over a reasonably short period of time?

A temporary budget of $1,000,000 has been approved. Except for one contract already in progress, no expenditure from that amount will be made for contract research or contract renewal.

ARTHUR J. STEVENS

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Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.*, 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

FOOD AND DRUG ADMINISTRATION ET AL. *v.* BROWN & WILLIAMSON TOBACCO CORP. ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

No. 98–1152. Argued December 1, 1999—Decided March 21, 2000

The Food, Drug, and Cosmetic Act (FDCA), 21 U. S. C. §301 *et seq.*, grants the Food and Drug Administration (FDA), as the designee of the Secretary of Health and Human Services (HHS), the authority to regulate, among other items, "drugs" and "devices," §§321(g)–(h), 393. In 1996 the FDA asserted jurisdiction to regulate tobacco products, concluding that, under the FDCA, nicotine is a "drug" and cigarettes and smokeless tobacco are "devices" that deliver nicotine to the body. Pursuant to this authority, the FDA promulgated regulations governing tobacco products' promotion, labeling, and accessibility to children and adolescents. The FDA found that tobacco use is the Nation's leading cause of premature death, resulting in more than 400,000 deaths annually, and that most adult smokers begin when they are minors. The regulations therefore aim to reduce tobacco use by minors so as to substantially reduce the prevalence of addiction in future generations, and thus the incidence of tobacco-related death and disease. Respondents, a group of tobacco manufacturers, retailers, and advertisers, filed this suit challenging the FDA's regulations. They moved for summary judgment on the ground, *inter alia*, that the FDA lacked jurisdiction to regulate tobacco products as customarily marketed, that is, without manufacturer claims of therapeutic benefit. The District Court upheld the FDA's authority, but the Fourth Circuit reversed, holding that Congress has not granted the FDA jurisdiction to regulate tobacco products. The court concluded that construing the FDCA to include tobacco products would lead to several internal inconsistencies in the Act. It also found that evidence external to the FDCA—that the FDA consistently stated before 1995 that it lacked jurisdiction over tobacco, that Congress has en-

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acted several tobacco-specific statutes fully cognizant of the FDA's position, and that Congress has considered and rejected many bills that would have given the agency such authority—confirms this conclusion.

Held: Reading the FDCA as a whole, as well as in conjunction with Congress' subsequent tobacco-specific legislation, it is plain that Congress has not given the FDA the authority to regulate tobacco products as customarily marketed. Pp. 8–40.

(a) Because this case involves an agency's construction of a statute it administers, the Court's analysis is governed by *Chevron U. S. A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U. S. 837, under which a reviewing court must first ask whether Congress has directly spoken to the precise question at issue, *id.*, at 842. If so, the court must give effect to Congress' unambiguously expressed intent. *E.g.*, *id.*, at 843. If not, the court must defer to the agency's construction of the statute so long as it is permissible. See, *e.g.*, *INS* v. *Aguirre-Aguirre*, 526 U. S. 415, 424. In determining whether Congress has specifically addressed the question at issue, the court should not confine itself to examining a particular statutory provision in isolation. Rather, it must place the provision in context, interpreting the statute to create a symmetrical and coherent regulatory scheme. *Gustafson* v. *Alloyd Co.*, 513 U. S. 561, 569. In addition, the meaning of one statute may be affected by other Acts, particularly where Congress has spoken subsequently and more specifically to the topic at hand. See, *e.g.*, *United States* v. *Estate of Romani*, 523 U. S. 517, 530–531. Finally, the court must be guided to a degree by common sense as to the manner in which Congress is likely to delegate a policy decision of such economic and political magnitude to an administrative agency. Cf. *MCI Telecommunications Corp.* v. *American Telephone & Telegraph Co.*, 512 U. S. 218, 231. Pp. 8–10.

(b) Considering the FDCA as a whole, it is clear that Congress intended to exclude tobacco products from the FDA's jurisdiction. A fundamental precept of the FDCA is that any product regulated by the FDA that remains on the market must be safe and effective for its intended use. See, *e.g.*, §393(b)(2). That is, the potential for inflicting death or physical injury must be offset by the possibility of therapeutic benefit. *United States* v. *Rutherford*, 442 U. S. 544, 556. In its rulemaking proceeding, the FDA quite exhaustively documented that tobacco products are unsafe, dangerous, and cause great pain and suffering from illness. These findings logically imply that, if tobacco products were "devices" under the FDCA, the FDA would be required to remove them from the market under the FDCA's misbranding, see, *e.g.*, §331(a), and device classification, see, *e.g.*, §360e(d)(2)(A), provisions. In fact, based on such provisions, the FDA itself has previously

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asserted that if tobacco products were within its jurisdiction, they would have to be removed from the market because it would be impossible to prove they were safe for their intended use. Congress, however, has foreclosed a ban of such products, choosing instead to create a distinct regulatory scheme focusing on the labeling and advertising of cigarettes and smokeless tobacco. Its express policy is to protect commerce and the national economy while informing consumers about any adverse health effects. See 15 U. S. C. §1331. Thus, an FDA ban would plainly contradict congressional intent. Apparently recognizing this dilemma, the FDA has concluded that tobacco products are actually "safe" under the FDCA because banning them would cause a greater harm to public health than leaving them on the market. But this safety determination—focusing on the relative harms caused by alternative remedial measures—is not a substitute for those required by the FDCA. Various provisions in the Act require the agency to determine that, at least for some consumers, the product's therapeutic benefits outweigh the risks of illness or serious injury. This the FDA cannot do, because tobacco products are unsafe for obtaining any therapeutic benefit. The inescapable conclusion is that there is no room for tobacco products within the FDCA's regulatory scheme. If they cannot be used safely for any therapeutic purpose, and yet they cannot be banned, they simply do not fit. Pp. 10–20.

(c) The history of tobacco-specific legislation also demonstrates that Congress has spoken directly to the FDA's authority to regulate tobacco products. Since 1965, Congress has enacted six separate statutes addressing the problem of tobacco use and human health. These statutes, among other things, require that health warnings appear on all packaging and in all print and outdoor advertisements, see 15 U. S. C. §§1331, 1333, 4402; prohibit the advertisement of tobacco products through any electronic communication medium regulated by the Federal Communications Commission, see §§1335, 4402(f); require the Secretary of HHS to report every three years to Congress on research findings concerning tobacco's addictive property, 42 U. S. C. §290aa–2(b)(2); and make States' receipt of certain federal block grants contingent on their prohibiting any tobacco product manufacturer, retailer, or distributor from selling or distributing any such product to individuals under age 18, §300x–26(a)(1). This tobacco-specific legislation has created a specific regulatory scheme for addressing the problem of tobacco and health. And it was adopted against the backdrop of the FDA consistently and resolutely stating that it was without authority under the FDCA to regulate tobacco products as customarily marketed. In fact, Congress several times considered and rejected bills that would have given the FDA

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Syllabus

such authority. Indeed, Congress' actions in this area have evidenced a clear intent to preclude a meaningful policymaking role for any administrative agency. Further, Congress' tobacco legislation prohibits any additional regulation of tobacco product labeling with respect to tobacco's health consequences, a central aspect of regulation under the FDCA. Under these circumstances, it is evident that Congress has ratified the FDA's previous, long-held position that it lacks jurisdiction to regulate tobacco products as customarily marketed. Congress has created a distinct scheme for addressing the subject, and that scheme excludes any role for FDA regulation. Pp. 20–37.

(d) Finally, the Court's inquiry is shaped, at least in some measure, by the nature of the question presented. *Chevron* deference is premised on the theory that a statute's ambiguity constitutes an implicit delegation from Congress to the agency to fill in the statutory gaps. See 467 U. S., at 844. In extraordinary cases, however, there may be reason to hesitate before concluding that Congress has intended such an implicit delegation. This is hardly an ordinary case. Contrary to the agency's position from its inception until 1995, the FDA has now asserted jurisdiction to regulate an industry constituting a significant portion of the American economy. In fact, the FDA contends that, were it to determine that tobacco products provide no "reasonable assurance of safety," it would have the authority to ban cigarettes and smokeless tobacco entirely. It is highly unlikely that Congress would leave the determination as to whether the sale of tobacco products would be regulated, or even banned, to the FDA's discretion in so cryptic a fashion. See *MCI Telecommunications*, 512 U. S., at 231. Given tobacco's unique political history, as well as the breadth of the authority that the FDA has asserted, the Court is obliged to defer not to the agency's expansive construction of the statute, but to Congress' consistent judgment to deny the FDA this power. Pp. 37–39.

(e) No matter how important, conspicuous, and controversial the issue, and regardless of how likely the public is to hold the Executive Branch politically accountable, an administrative agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress. Courts must take care not to extend a statute's scope beyond the point where Congress indicated it would stop. *E.g., United States* v. *Article of Drug . . . Bacto-Unidisk*, 394 U. S. 784, 800. P. 40.

153 F. 3d 155, affirmed.

O'CONNOR, J., delivered the opinion of the Court, in which REHNQUIST, C. J., and SCALIA, KENNEDY, and THOMAS, JJ., joined. BREYER, J., filed a dissenting opinion, in which STEVENS, SOUTER, and GINSBURG, JJ., joined.

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SUPREME COURT OF THE UNITED STATES

No. 98–1152

FOOD AND DRUG ADMINISTRATION, ET AL., PETITIONERS *v.* BROWN & WILLIAMSON TOBACCO CORPORATION ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

[March 21, 2000]

JUSTICE O'CONNOR delivered the opinion of the Court.

This case involves one of the most troubling public health problems facing our Nation today: the thousands of premature deaths that occur each year because of tobacco use. In 1996, the Food and Drug Administration (FDA), after having expressly disavowed any such authority since its inception, asserted jurisdiction to regulate tobacco products. See 61 Fed. Reg. 44619–45318. The FDA concluded that nicotine is a "drug" within the meaning of the Food, Drug, and Cosmetic Act (FDCA or Act), 52 Stat. 1040, as amended, 21 U. S. C. §301 *et seq.*, and that cigarettes and smokeless tobacco are "combination products" that deliver nicotine to the body. 61 Fed. Reg. 44397 (1996). Pursuant to this authority, it promulgated regulations intended to reduce tobacco consumption among children and adolescents. *Id.*, at 44615–44618. The agency believed that, because most tobacco consumers begin their use before reaching the age of 18, curbing tobacco use by minors could substantially reduce the prevalence of addiction in future generations and thus the incidence of tobacco-related death and disease. *Id.*, at

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44398–44399.

Regardless of how serious the problem an administrative agency seeks to address, however, it may not exercise its authority "in a manner that is inconsistent with the administrative structure that Congress enacted into law." *ETSI Pipeline Project* v. *Missouri*, 484 U. S. 495, 517 (1988). And although agencies are generally entitled to deference in the interpretation of statutes that they administer, a reviewing court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron U. S. A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U. S. 837, 842–843 (1984). In this case, we believe that Congress has clearly precluded the FDA from asserting jurisdiction to regulate tobacco products. Such authority is inconsistent with the intent that Congress has expressed in the FDCA's overall regulatory scheme and in the tobacco-specific legislation that it has enacted subsequent to the FDCA. In light of this clear intent, the FDA's assertion of jurisdiction is impermissible.

I

The FDCA grants the FDA, as the designee of the Secretary of Health and Human Services, the authority to regulate, among other items, "drugs" and "devices." See 21 U. S. C. §§321(g)–(h), 393 (1994 ed. and Supp. III). The Act defines "drug" to include "articles (other than food) intended to affect the structure or any function of the body." 21 U. S. C. §321(g)(1)(C). It defines "device," in part, as "an instrument, apparatus, implement, machine, contrivance, . . . or other similar or related article, including any component, part, or accessory, which is . . . intended to affect the structure or any function of the body." §321(h). The Act also grants the FDA the authority to regulate so-called "combination products," which "constitute a combination of a drug, device, or biologic product."

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§353(g)(1). The FDA has construed this provision as giving it the discretion to regulate combination products as drugs, as devices, or as both. See 61 Fed. Reg. 44400 (1996).

On August 11, 1995, the FDA published a proposed rule concerning the sale of cigarettes and smokeless tobacco to children and adolescents. 60 Fed. Reg. 41314–41787. The rule, which included several restrictions on the sale, distribution, and advertisement of tobacco products, was designed to reduce the availability and attractiveness of tobacco products to young people. *Id.*, at 41314. A public comment period followed, during which the FDA received over 700,000 submissions, more than "at any other time in its history on any other subject." 61 Fed. Reg. 44418 (1996).

On August 28, 1996, the FDA issued a final rule entitled "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents." *Id.*, at 44396. The FDA determined that nicotine is a "drug" and that cigarettes and smokeless tobacco are "drug delivery devices," and therefore it had jurisdiction under the FDCA to regulate tobacco products as customarily marketed—that is, without manufacturer claims of therapeutic benefit. *Id.*, at 44397, 44402. First, the FDA found that tobacco products "'affect the structure or any function of the body'" because nicotine "has significant pharmacological effects." *Id.*, at 44631. Specifically, nicotine "exerts psychoactive, or mood-altering, effects on the brain" that cause and sustain addiction, have both tranquilizing and stimulating effects, and control weight. *Id.*, at 44631–44632. Second, the FDA determined that these effects were "intended" under the FDCA because they "are so widely known and foreseeable that [they] may be deemed to have been intended by the manufacturers," *id.*, at 44687; consumers use tobacco products "predominantly or nearly exclusively" to obtain these effects, *id.*, at

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44807; and the statements, research, and actions of manufacturers revealed that they "have 'designed' cigarettes to provide pharmacologically active doses of nicotine to consumers," *id.*, at 44849. Finally, the agency concluded that cigarettes and smokeless tobacco are "combination products" because, in addition to containing nicotine, they include device components that deliver a controlled amount of nicotine to the body, *id.*, at 45208–45216.

Having resolved the jurisdictional question, the FDA next explained the policy justifications for its regulations, detailing the deleterious health effects associated with tobacco use. It found that tobacco consumption was "the single leading cause of preventable death in the United States." *Id.*, at 44398. According to the FDA, "[m]ore than 400,000 people die each year from tobacco-related illnesses, such as cancer, respiratory illnesses, and heart disease." *Ibid.* The agency also determined that the only way to reduce the amount of tobacco-related illness and mortality was to reduce the level of addiction, a goal that could be accomplished only by preventing children and adolescents from starting to use tobacco. *Id.*, at 44398–44399. The FDA found that 82% of adult smokers had their first cigarette before the age of 18, and more than half had already become regular smokers by that age. *Id.*, at 44398. It also found that children were beginning to smoke at a younger age, that the prevalence of youth smoking had recently increased, and that similar problems existed with respect to smokeless tobacco. *Id.*, at 44398–44399. The FDA accordingly concluded that if "the number of children and adolescents who begin tobacco use can be substantially diminished, tobacco-related illness can be correspondingly reduced because data suggest that anyone who does not begin smoking in childhood or adolescence is unlikely ever to begin." *Id.*, at 44399.

Based on these findings, the FDA promulgated regulations concerning tobacco products' promotion, labeling,

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and accessibility to children and adolescents. See *id.*, at 44615–44618. The access regulations prohibit the sale of cigarettes or smokeless tobacco to persons younger than 18; require retailers to verify through photo identification the age of all purchasers younger than 27; prohibit the sale of cigarettes in quantities smaller than 20; prohibit the distribution of free samples; and prohibit sales through self-service displays and vending machines except in adult-only locations. *Id.*, at 44616–44617. The promotion regulations require that any print advertising appear in a black-and-white, text-only format unless the publication in which it appears is read almost exclusively by adults; prohibit outdoor advertising within 1,000 feet of any public playground or school; prohibit the distribution of any promotional items, such as T-shirts or hats, bearing the manufacturer's brand name; and prohibit a manufacturer from sponsoring any athletic, musical, artistic, or other social or cultural event using its brand name. *Id.*, at 44617–44618. The labeling regulation requires that the statement, "A Nicotine-Delivery Device for Persons 18 or Older," appear on all tobacco product packages. *Id.*, at 44617.

The FDA promulgated these regulations pursuant to its authority to regulate "restricted devices." See 21 U. S. C. §360j(e). The FDA construed §353(g)(1) as giving it the discretion to regulate "combination products" using the Act's drug authorities, device authorities, or both, depending on "how the public health goals of the act can be best accomplished." 61 Fed. Reg. 44403 (1996). Given the greater flexibility in the FDCA for the regulation of devices, the FDA determined that "the device authorities provide the most appropriate basis for regulating cigarettes and smokeless tobacco." *Id.*, at 44404. Under 21 U. S. C. §360j(e), the agency may "require that a device be restricted to sale, distribution, or use . . . upon such other conditions as [the FDA] may prescribe in such regulation,

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if, because of its potentiality for harmful effect or the collateral measures necessary to its use, [the FDA] determines that there cannot otherwise be reasonable assurance of its safety and effectiveness." The FDA reasoned that its regulations fell within the authority granted by §360j(e) because they related to the sale or distribution of tobacco products and were necessary for providing a reasonable assurance of safety. 61 Fed. Reg. 44405–44407 (1996).

Respondents, a group of tobacco manufacturers, retailers, and advertisers, filed suit in United States District Court for the Middle District of North Carolina challenging the regulations. See *Coyne Beahm, Inc.* v. *FDA*, 966 F. Supp. 1374 (1997). They moved for summary judgment on the grounds that the FDA lacked jurisdiction to regulate tobacco products as customarily marketed, the regulations exceeded the FDA's authority under 21 U. S. C. §360j(e), and the advertising restrictions violated the First Amendment. Second Brief in Support of Plaintiffs' Motion for Summary Judgment in No. 2:95CV00591 (MDNC), in 3 Rec. in No. 97–1604 (CA4), Tab No. 40; Third Brief in Support of Plaintiffs' Motion for Summary Judgment in No. 2:95CV00591 (MDNC), in 3 Rec. in No. 97–1604 (CA4), Tab No. 42. The District Court granted respondents' motion in part and denied it in part. 966 F. Supp., at 1400. The court held that the FDCA authorizes the FDA to regulate tobacco products as customarily marketed and that the FDA's access and labeling regulations are permissible, but it also found that the agency's advertising and promotion restrictions exceed its authority under §360j(e). *Id.*, at 1380–1400. The court stayed implementation of the regulations it found valid (except the prohibition on the sale of tobacco products to minors) and certified its order for immediate interlocutory appeal. *Id.*, at 1400–1401.

The Court of Appeals for the Fourth Circuit reversed,

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holding that Congress has not granted the FDA jurisdiction to regulate tobacco products. See 153 F. 3d 155 (1998). Examining the FDCA as a whole, the court concluded that the FDA's regulation of tobacco products would create a number of internal inconsistencies. *Id.*, at 162–167. Various provisions of the Act require the agency to determine that any regulated product is "safe" before it can be sold or allowed to remain on the market, yet the FDA found in its rulemaking proceeding that tobacco products are "dangerous" and "unsafe." *Id.*, at 164–167. Thus, the FDA would apparently have to ban tobacco products, a result the court found clearly contrary to congressional intent. *Ibid.* This apparent anomaly, the Court of Appeals concluded, demonstrates that Congress did not intend to give the FDA authority to regulate tobacco. *Id.*, at 167. The court also found that evidence external to the FDCA confirms this conclusion. Importantly, the FDA consistently stated before 1995 that it lacked jurisdiction over tobacco, and Congress has enacted several tobacco-specific statutes fully cognizant of the FDA's position. See *id.*, at 168–176. In fact, the court reasoned, Congress has considered and rejected many bills that would have given the agency such authority. See *id.*, at 170–171. This, along with the absence of any intent by the enacting Congress in 1938 to subject tobacco products to regulation under the FDCA, demonstrates that Congress intended to withhold such authority from the FDA. *Id.*, at 167–176. Having resolved the jurisdictional question against the agency, the Court of Appeals did not address whether the regulations exceed the FDA's authority under 21 U. S. C. §360j(e) or violate the First Amendment. See 153 F. 3d, at 176, n. 29.

We granted the Government's petition for certiorari, 526 U. S. 1086 (1999), to determine whether the FDA has authority under the FDCA to regulate tobacco products as customarily marketed.

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II

The FDA's assertion of jurisdiction to regulate tobacco products is founded on its conclusions that nicotine is a "drug" and that cigarettes and smokeless tobacco are "drug delivery devices." Again, the FDA found that tobacco products are "intended" to deliver the pharmacological effects of satisfying addiction, stimulation and tranquilization, and weight control because those effects are foreseeable to any reasonable manufacturer, consumers use tobacco products to obtain those effects, and tobacco manufacturers have designed their products to produce those effects. 61 Fed. Reg. 44632–44633 (1996). As an initial matter, respondents take issue with the FDA's reading of "intended," arguing that it is a term of art that refers exclusively to claims made by the manufacturer or vendor about the product. See Brief for Respondent Brown & Williamson Tobacco Corp. 6. That is, a product is not a drug or device under the FDCA unless the manufacturer or vendor makes some express claim concerning the product's therapeutic benefits. See *id.*, at 6–7. We need not resolve this question, however, because assuming, *arguendo*, that a product can be "intended to affect the structure or any function of the body" absent claims of therapeutic or medical benefit, the FDA's claim to jurisdiction contravenes the clear intent of Congress.

A threshold issue is the appropriate framework for analyzing the FDA's assertion of authority to regulate tobacco products. Because this case involves an administrative agency's construction of a statute that it administers, our analysis is governed by *Chevron U. S. A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U. S. 837 (1984). Under *Chevron*, a reviewing court must first ask "whether Congress has directly spoken to the precise question at issue." *Id.*, at 842. If Congress has done so, the

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inquiry is at an end; the court "must give effect to the unambiguously expressed intent of Congress." *Id.*, at 843; see also *United States* v. *Haggar Apparel Co.*, 526 U. S. 380, 392 (1999); *Holly Farms Corp.* v. *NLRB*, 517 U. S. 392, 398 (1996). But if Congress has not specifically addressed the question, a reviewing court must respect the agency's construction of the statute so long as it is permissible. See *INS* v. *Aguirre-Aguirre*, 526 U. S. 415, 424 (1999); *Auer* v. *Robbins*, 519 U. S. 452, 457 (1997). Such deference is justified because "[t]he responsibilities for assessing the wisdom of such policy choices and resolving the struggle between competing views of the public interest are not judicial ones," *Chevron*, *supra*, at 866, and because of the agency's greater familiarity with the ever-changing facts and circumstances surrounding the subjects regulated, see *Rust* v. *Sullivan*, 500 U. S. 173, 187 (1991).

In determining whether Congress has specifically addressed the question at issue, a reviewing court should not confine itself to examining a particular statutory provision in isolation. The meaning—or ambiguity—of certain words or phrases may only become evident when placed in context. See *Brown* v. *Gardner*, 513 U. S. 115, 118 (1994) ("Ambiguity is a creature not of definitional possibilities but of statutory context"). It is a "fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *Davis* v. *Michigan Dept. of Treasury*, 489 U. S. 803, 809 (1989). A court must therefore interpret the statute "as a symmetrical and coherent regulatory scheme," *Gustafson* v. *Alloyd Co.*, 513 U. S. 561, 569 (1995), and "fit, if possible, all parts into an harmonious whole," *FTC* v. *Mandel Brothers, Inc.*, 359 U. S. 385, 389 (1959). Similarly, the meaning of one statute may be affected by other Acts, particularly where Congress has spoken subsequently and more specifically to the topic at hand. See *United States* v. *Estate of Romani*, 523 U. S. 517, 530–531

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(1998); *United States* v. *Fausto*, 484 U. S. 439, 453 (1988). In addition, we must be guided to a degree by common sense as to the manner in which Congress is likely to delegate a policy decision of such economic and political magnitude to an administrative agency. Cf. *MCI Telecommunications Corp.* v. *American Telephone & Telegraph Co.*, 512 U. S. 218, 231 (1994).

With these principles in mind, we find that Congress has directly spoken to the issue here and precluded the FDA's jurisdiction to regulate tobacco products.

A

Viewing the FDCA as a whole, it is evident that one of the Act's core objectives is to ensure that any product regulated by the FDA is "safe" and "effective" for its intended use. See 21 U. S. C. §393(b)(2) (1994 ed., Supp. III) (defining the FDA's mission); More Information for Better Patient Care: Hearing before the Senate Committee on Labor and Human Resources, 104th Cong., 2d Sess., 83 (1996) (statement of FDA Deputy Commissioner Schultz) ("A fundamental precept of drug and device regulation in this country is that these products must be proven safe and effective before they can be sold"). This essential purpose pervades the FDCA. For instance, 21 U. S. C. §393(b)(2) (1994 ed., Supp. III) defines the FDA's "mission" to include "protect[ing] the public health by ensuring that . . . drugs are safe and effective" and that "there is reasonable assurance of the safety and effectiveness of devices intended for human use." The FDCA requires premarket approval of any new drug, with some limited exceptions, and states that the FDA "shall issue an order refusing to approve the application" of a new drug if it is not safe and effective for its intended purpose. §§355(d)(1)–(2), (4)–(5). If the FDA discovers after approval that a drug is unsafe or ineffective, it "shall, after due notice and opportunity

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for hearing to the applicant, withdraw approval" of the drug. 21 U. S. C. §§355(e)(1)–(3). The Act also requires the FDA to classify all devices into one of three categories. §360c(b)(1). Regardless of which category the FDA chooses, there must be a "reasonable assurance of the safety and effectiveness of the device." 21 U. S. C. §§360c(a)(1)(A)(i), (B), (C) (1994 ed. and Supp. III); 61 Fed. Reg. 44412 (1996). Even the "restricted device" provision pursuant to which the FDA promulgated the regulations at issue here authorizes the agency to place conditions on the sale or distribution of a device specifically when "there cannot otherwise be reasonable assurance of its safety and effectiveness." 21 U. S. C. §360j(e). Thus, the Act generally requires the FDA to prevent the marketing of any drug or device where the "potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit." *United States* v. *Rutherford*, 442 U. S. 544, 556 (1979).

In its rulemaking proceeding, the FDA quite exhaustively documented that "tobacco products are unsafe," "dangerous," and "cause great pain and suffering from illness." 61 Fed. Reg. 44412 (1996). It found that the consumption of tobacco products "presents extraordinary health risks," and that "tobacco use is the single leading cause of preventable death in the United States." *Id.*, at 44398. It stated that "[m]ore than 400,000 people die each year from tobacco-related illnesses, such as cancer, respiratory illnesses, and heart disease, often suffering long and painful deaths," and that "[t]obacco alone kills more people each year in the United States than acquired immunodeficiency syndrome (AIDS), car accidents, alcohol, homicides, illegal drugs, suicides, and fires, combined." *Ibid.* Indeed, the FDA characterized smoking as "a pediatric disease," *id.*, at 44421, because "one out of every three young people who become regular smokers . . . will die prematurely as a result," *id.*, at 44399.

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These findings logically imply that, if tobacco products were "devices" under the FDCA, the FDA would be required to remove them from the market. Consider, first, the FDCA's provisions concerning the misbranding of drugs or devices. The Act prohibits "[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded." 21 U. S. C. §331(a). In light of the FDA's findings, two distinct FDCA provisions would render cigarettes and smokeless tobacco misbranded devices. First, §352(j) deems a drug or device misbranded "[i]f it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." The FDA's findings make clear that tobacco products are "dangerous to health" when used in the manner prescribed. Second, a drug or device is misbranded under the Act "[u]nless its labeling bears . . . adequate directions for use . . . in such manner and form, as are necessary for the protection of users," except where such directions are "not necessary for the protection of the public health." §352(f)(1). Given the FDA's conclusions concerning the health consequences of tobacco use, there are no directions that could adequately protect consumers. That is, there are no directions that could make tobacco products safe for obtaining their intended effects. Thus, were tobacco products within the FDA's jurisdiction, the Act would deem them misbranded devices that could not be introduced into interstate commerce. Contrary to the dissent's contention, the Act admits no remedial discretion once it is evident that the device is misbranded.

Second, the FDCA requires the FDA to place all devices that it regulates into one of three classifications. See §360c(b)(1). The agency relies on a device's classification in determining the degree of control and regulation necessary to ensure that there is "a reasonable assurance of

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safety and effectiveness." 61 Fed. Reg. 44412 (1996). The FDA has yet to classify tobacco products. Instead, the regulations at issue here represent so-called "general controls," which the Act entitles the agency to impose in advance of classification. See *id.*, at 44404–44405. Although the FDCA prescribes no deadline for device classification, the FDA has stated that it will classify tobacco products "in a future rulemaking" as required by the Act. *Id.*, at 44412. Given the FDA's findings regarding the health consequences of tobacco use, the agency would have to place cigarettes and smokeless tobacco in Class III because, even after the application of the Act's available controls, they would "presen[t] a potential unreasonable risk of illness or injury." 21 U. S. C. §360c(a)(1)(C). As Class III devices, tobacco products would be subject to the FDCA's premarket approval process. See 21 U. S. C. §360c(a)(1)(C) (1994 ed., Supp. III); 21 U. S. C. §360e; 61 Fed. Reg. 44412 (1996). Under these provisions, the FDA would be prohibited from approving an application for premarket approval without "a showing of reasonable assurance that such device is safe under the conditions of use prescribed, recommended, or suggested on the labeling thereof." 21 U. S. C. §360e(d)(2)(A). In view of the FDA's conclusions regarding the health effects of tobacco use, the agency would have no basis for finding any such reasonable assurance of safety. Thus, once the FDA fulfilled its statutory obligation to classify tobacco products, it could not allow them to be marketed.

The FDCA's misbranding and device classification provisions therefore make evident that were the FDA to regulate cigarettes and smokeless tobacco, the Act would require the agency to ban them. In fact, based on these provisions, the FDA itself has previously taken the position that if tobacco products were within its jurisdiction, "they would have to be removed from the market because it would be impossible to prove they were safe for their

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intended us[e]." Public Health Cigarette Amendments of 1971: Hearings before the Commerce Subcommittee on S. 1454, 92d Cong., 2d Sess., 239 (1972) (hereinafter 1972 Hearings) (statement of FDA Commissioner Charles Edwards). See also Cigarette Labeling and Advertising: Hearings before the House Committee on Interstate and Foreign Commerce, 88th Cong., 2d Sess., 18 (1964) (hereinafter 1964 Hearings) (statement of Department of Health, Education, and Welfare (HEW) Secretary Anthony Celebrezze that proposed amendments to the FDCA that would have given the FDA jurisdiction over "smoking product[s]" "might well completely outlaw at least cigarettes").

Congress, however, has foreclosed the removal of tobacco products from the market. A provision of the United States Code currently in force states that "[t]he marketing of tobacco constitutes one of the greatest basic industries of the United States with ramifying activities which directly affect interstate and foreign commerce at every point, and stable conditions therein are necessary to the general welfare." 7 U. S. C. §1311(a). More importantly, Congress has directly addressed the problem of tobacco and health through legislation on six occasions since 1965. See Federal Cigarette Labeling and Advertising Act (FCLAA), Pub. L. 89–92, 79 Stat. 282; Public Health Cigarette Smoking Act of 1969, Pub. L. 91–222, 84 Stat. 87; Alcohol and Drug Abuse Amendments of 1983, Pub. L. 98–24, 97 Stat. 175; Comprehensive Smoking Education Act, Pub. L. 98–474, 98 Stat. 2200; Comprehensive Smokeless Tobacco Health Education Act of 1986, Pub. L. 99–252, 100 Stat. 30; Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act, Pub. L. 102–321, §202, 106 Stat. 394. When Congress enacted these statutes, the adverse health consequences of tobacco use were well known, as were nicotine's pharmacological effects. See, *e.g.*, U. S. Dept. of Health, Education, and Welfare, U. S. Surgeon

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General's Advisory Committee, Smoking and Health 25–40, 69–75 (1964) (hereinafter 1964 Surgeon General's Report) (concluding that cigarette smoking causes lung cancer, coronary artery disease, and chronic bronchitis and emphysema, and that nicotine has various pharmacological effects, including stimulation, tranquilization, and appetite suppression); U. S. Dept. of Health and Human Services, Public Health Service, Health Consequences of Smoking for Women 7–12 (1980) (finding that mortality rates for lung cancer, chronic lung disease, and coronary heart disease are increased for both women and men smokers, and that smoking during pregnancy is associated with significant adverse health effects on the unborn fetus and newborn child); U. S. Dept. of Health and Human Services, Public Health Service, Why People Smoke Cigarettes (1983), in Smoking Prevention Education Act, Hearings on H. R. 1824 before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce, 98th Cong., 1st Sess., 32–37 (1983) (hereinafter 1983 House Hearings) (stating that smoking is "the most widespread example of drug dependence in our country," and that cigarettes "affect the chemistry of the brain and nervous system"); U. S. Dept. of Health and Human Services, Public Health Service, The Health Consequences of Smoking: Nicotine Addiction 6–9, 145–239 (1988) (hereinafter 1988 Surgeon General's Report) (concluding that tobacco products are addicting in much the same way as heroin and cocaine, and that nicotine is the drug that causes addiction). Nonetheless, Congress stopped well short of ordering a ban. Instead, it has generally regulated the labeling and advertisement of tobacco products, expressly providing that it is the policy of Congress that "commerce and the national economy may be . . . protected to the maximum extent consistent with" consumers "be[ing] adequately informed about any adverse health effects." 15 U. S. C. §1331. Congress'

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decisions to regulate labeling and advertising and to adopt the express policy of protecting "commerce and the national economy . . . to the maximum extent" reveal its intent that tobacco products remain on the market. Indeed, the collective premise of these statutes is that cigarettes and smokeless tobacco will continue to be sold in the United States. A ban of tobacco products by the FDA would therefore plainly contradict congressional policy.

The FDA apparently recognized this dilemma and concluded, somewhat ironically, that tobacco products are actually "safe" within the meaning of the FDCA. In promulgating its regulations, the agency conceded that "tobacco products are unsafe, as that term is conventionally understood." 61 Fed. Reg. 44412 (1996). Nonetheless, the FDA reasoned that, in determining whether a device is safe under the Act, it must consider "not only the risks presented by a product but also any of the countervailing effects of use of that product, including the consequences of not permitting the product to be marketed." *Id.*, at 44412–44413. Applying this standard, the FDA found that, because of the high level of addiction among tobacco users, a ban would likely be "dangerous." *Id.*, at 44413. In particular, current tobacco users could suffer from extreme withdrawal, the health care system and available pharmaceuticals might not be able to meet the treatment demands of those suffering from withdrawal, and a black market offering cigarettes even more dangerous than those currently sold legally would likely develop. *Ibid.* The FDA therefore concluded that, "while taking cigarettes and smokeless tobacco off the market could prevent some people from becoming addicted and reduce death and disease for others, the record does not establish that such a ban is the appropriate public health response under the act." *Id.*, at 44398.

It may well be, as the FDA asserts, that "these factors must be considered when developing a regulatory scheme

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that achieves the best public health result for these products." *Id.*, at 44413. But the FDA's judgment that leaving tobacco products on the market "is more effective in achieving public health goals than a ban," *ibid.*, is no substitute for the specific safety determinations required by the FDCA's various operative provisions. Several provisions in the Act require the FDA to determine that the *product itself* is safe as used by consumers. That is, the product's probable therapeutic benefits must outweigh its risk of harm. See *United States* v. *Rutherford,* 442 U. S., at 555 ("[T]he Commissioner generally considers a drug safe when the expected therapeutic gain justifies the risk entailed by its use"). In contrast, the FDA's conception of safety would allow the agency, with respect to each provision of the FDCA that requires the agency to determine a product's "safety" or "dangerousness," to compare the aggregate health effects of alternative administrative actions. This is a qualitatively different inquiry. Thus, although the FDA has concluded that a ban would be "dangerous," it has *not* concluded that tobacco products are "safe" as that term is used throughout the Act.

Consider 21 U. S. C. §360c(a)(2), which specifies those factors that the FDA may consider in determining the safety and effectiveness of a device for purposes of classification, performance standards, and premarket approval. For all devices regulated by the FDA, there must at least be a "reasonable assurance of the safety and effectiveness of the device." See 21 U. S. C. §§360c(a)(1)(A)(i), (B), (C) (1994 ed. and Supp. III); 61 Fed. Reg. 44412 (1996). Title 21 U. S. C. §360c(a)(2) provides that

> "the safety and effectiveness of a device are to be determined—
>
> "(A) with respect to the persons for whose use the device is represented or intended,
>
> "(B) with respect to the conditions of use prescribed,

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recommended, or suggested in the labeling of the device, and

"(C) weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use."

A straightforward reading of this provision dictates that the FDA must weigh the probable therapeutic benefits of the device to the consumer against the probable risk of injury. Applied to tobacco products, the inquiry is whether their purported benefits—satisfying addiction, stimulation and sedation, and weight control—outweigh the risks to health from their use. To accommodate the FDA's conception of safety, however, one must read "any probable benefit to health" to include the benefit to public health stemming from adult consumers' continued use of tobacco products, even though the *reduction* of tobacco use is the *raison d'être* of the regulations. In other words, the FDA is forced to contend that the very evil it seeks to combat is a "benefit to health." This is implausible.

The FDA's conception of safety is also incompatible with the FDCA's misbranding provision. Again, §352(j) provides that a product is "misbranded" if "it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." According to the FDA's understanding, a product would be "dangerous to health," and therefore misbranded under §352(j), when, in comparison to leaving the product on the market, a ban would not produce "adverse health consequences" in aggregate. Quite simply, these are different inquiries. Although banning a particular product might be detrimental to public health in aggregate, the product could still be "dangerous to health" when used as directed. Section 352(j) focuses on dangers to the consumer from use of the product, not those stemming from the agency's remedial meas-

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ures.

Consequently, the analogy made by the FDA and the dissent to highly toxic drugs used in the treatment of various cancers is unpersuasive. See 61 Fed. Reg. 44413 (1996); *post*, at 17 (opinion of BREYER, J.). Although "dangerous" in some sense, these drugs are safe within the meaning of the Act because, for certain patients, the therapeutic benefits outweigh the risk of harm. Accordingly, such drugs cannot properly be described as "dangerous to health" under 21 U. S. C. §352(j). The same is not true for tobacco products. As the FDA has documented in great detail, cigarettes and smokeless tobacco are an unsafe means to obtaining *any* pharmacological effect.

The dissent contends that our conclusion means that "the FDCA requires the FDA to ban outright 'dangerous' drugs or devices," *post*, at 14, and that this is a "perverse" reading of the statute, *id.*, at 14, 21. This misunderstands our holding. The FDA, consistent with the FDCA, may clearly regulate many "dangerous" products without banning them. Indeed, virtually every drug or device poses dangers under certain conditions. What the FDA may not do is conclude that a drug or device cannot be used safely for any therapeutic purpose and yet, at the same time, allow that product to remain on the market. Such regulation is incompatible with the FDCA's core objective of ensuring that every drug or device is safe and effective.

Considering the FDCA as a whole, it is clear that Congress intended to exclude tobacco products from the FDA's jurisdiction. A fundamental precept of the FDCA is that any product regulated by the FDA—but not banned—must be safe for its intended use. Various provisions of the Act make clear that this refers to the safety of using the product to obtain its intended effects, not the public health ramifications of alternative administrative actions by the FDA. That is, the FDA must determine that there is a reasonable assurance that the product's therapeutic bene-

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fits outweigh the risk of harm to the consumer. According to this standard, the FDA has concluded that, although tobacco products might be effective in delivering certain pharmacological effects, they are "unsafe" and "dangerous" when used for these purposes. Consequently, if tobacco products were within the FDA's jurisdiction, the Act would require the FDA to remove them from the market entirely. But a ban would contradict Congress' clear intent as expressed in its more recent, tobacco-specific legislation. The inescapable conclusion is that there is no room for tobacco products within the FDCA's regulatory scheme. If they cannot be used safely for any therapeutic purpose, and yet they cannot be banned, they simply do not fit.

B

In determining whether Congress has spoken directly to the FDA's authority to regulate tobacco, we must also consider in greater detail the tobacco-specific legislation that Congress has enacted over the past 35 years. At the time a statute is enacted, it may have a range of plausible meanings. Over time, however, subsequent acts can shape or focus those meanings. The "classic judicial task of reconciling many laws enacted over time, and getting them to 'make sense' in combination, necessarily assumes that the implications of a statute may be altered by the implications of a later statute." *United States* v. *Fausto*, 484 U. S., at 453. This is particularly so where the scope of the earlier statute is broad but the subsequent statutes more specifically address the topic at hand. As we recognized recently in *United States* v. *Estate of Romani*, "a specific policy embodied in a later federal statute should control our construction of the [earlier] statute, even though it ha[s] not been expressly amended." 523 U. S., at 530–531.

Congress has enacted six separate pieces of legislation

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since 1965 addressing the problem of tobacco use and human health. See *supra*, at 14. Those statutes, among other things, require that health warnings appear on all packaging and in all print and outdoor advertisements, see 15 U. S. C. §§1331, 1333, 4402; prohibit the advertisement of tobacco products through "any medium of electronic communication" subject to regulation by the Federal Communications Commission (FCC), see §§1335, 4402(f); require the Secretary of Health and Human Services (HHS) to report every three years to Congress on research findings concerning "the addictive property of tobacco," 42 U. S. C. §290aa–2(b)(2); and make States' receipt of certain federal block grants contingent on their making it unlawful "for any manufacturer, retailer, or distributor of tobacco products to sell or distribute any such product to any individual under the age of 18," §300x–26(a)(1).

In adopting each statute, Congress has acted against the backdrop of the FDA's consistent and repeated statements that it lacked authority under the FDCA to regulate tobacco absent claims of therapeutic benefit by the manufacturer. In fact, on several occasions over this period, and after the health consequences of tobacco use and nicotine's pharmacological effects had become well known, Congress considered and rejected bills that would have granted the FDA such jurisdiction. Under these circumstances, it is evident that Congress' tobacco-specific statutes have effectively ratified the FDA's long-held position that it lacks jurisdiction under the FDCA to regulate tobacco products. Congress has created a distinct regulatory scheme to address the problem of tobacco and health, and that scheme, as presently constructed, precludes any role for the FDA.

On January 11, 1964, the Surgeon General released the report of the Advisory Committee on Smoking and Health. That report documented the deleterious health effects of

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smoking in great detail, concluding, in relevant part, "that cigarette smoking contributes substantially to mortality from certain specific diseases and to the overall death rate." 1964 Surgeon General's Report 31. It also identified the pharmacological effects of nicotine, including "stimulation," "tranquilization," and "suppression of appetite." *Id.*, at 74–75. Seven days after the report's release, the Federal Trade Commission (FTC) issued a notice of proposed rulemaking, see 29 Fed. Reg. 530–532 (1964), and in June 1964, the FTC promulgated a final rule requiring cigarette manufacturers "to disclose, clearly and prominently, in all advertising and on every pack, box, carton or other container . . . that cigarette smoking is dangerous to health and may cause death from cancer and other diseases," *id.*, at 8325. The rule was to become effective January 1, 1965, but, on a request from Congress, the FTC postponed enforcement for six months. See *Cipollone v. Liggett Group, Inc.*, 505 U. S. 504, 513–514 (1992).

In response to the Surgeon General's report and the FTC's proposed rule, Congress convened hearings to consider legislation addressing "the tobacco problem." 1964 Hearings 1. During those deliberations, FDA representatives testified before Congress that the agency lacked jurisdiction under the FDCA to regulate tobacco products. Surgeon General Terry was asked during hearings in 1964 whether HEW had the "authority to brand or label the packages of cigarettes or to control the advertising there." *Id.*, at 56. The Surgeon General stated that "we do not have such authority in existing laws governing the . . . Food and Drug Administration." *Ibid.* Similarly, FDA Deputy Commissioner Rankin testified in 1965 that "[t]he Food and Drug Administration has no jurisdiction under the Food, Drug, and Cosmetic Act over tobacco, unless it bears drug claims." Cigarette Labeling and Advertising—1965: Hearings on H. R. 2248 before the House Committee on Interstate and Foreign Commerce, 89th Cong., 1st

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Sess., 193 (hereinafter 1965 Hearings). See also Letter to Directors of Bureaus, Divisions and Directors of Districts from FDA Bureau of Enforcement (May 24, 1963), in 1972 Hearings 240 ("[T]obacco marketed for chewing or smoking without accompanying therapeutic claims, does not meet the definitions in the Food, Drug, and Cosmetic Act for food, drug, device or cosmetic"). In fact, HEW Secretary Celebrezze urged Congress *not* to amend the FDCA to cover "smoking products" because, in light of the findings in the Surgeon General's report, such a "provision might well completely outlaw at least cigarettes. This would be contrary to what, we understand, is intended or what, in the light of our experience with the 18th amendment, would be acceptable to the American people." 1964 Hearings 18.

The FDA's disavowal of jurisdiction was consistent with the position that it had taken since the agency's inception. As the FDA concedes, it never asserted authority to regulate tobacco products as customarily marketed until it promulgated the regulations at issue here. See Brief for Petitioners 37; see also Brief for Appellee (FDA) in *Action on Smoking and Health* v. *Harris*, 655 F. 2d 236 (CADC 1980), in 9 Rec. in No. 97–1604 (CA4), Tab No. 4, pp. 14–15 ("In the 73 years since the enactment of the original Food and Drug Act, and in the 41 years since the promulgation of the modern Food, Drug, and Cosmetic Act, the FDA has repeatedly informed Congress that cigarettes are beyond the scope of the statute absent health claims establishing a therapeutic intent on behalf of the manufacturer or vendor").

The FDA's position was also consistent with Congress' specific intent when it enacted the FDCA. Before the Act's adoption in 1938, the FDA's predecessor agency, the Bureau of Chemistry, announced that it lacked authority to regulate tobacco products under the Pure Food and Drug Act of 1906, ch. 3915, 34 Stat. 768, unless they were mar-

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keted with therapeutic claims. See U. S. Dept. of Agriculture, Bureau of Chemistry, 13 Service and Regulatory Announcements 24 (Apr. 1914) (Feb. 1914 Announcements ¶13, Opinion of Chief of Bureau C. L. Alsberg). In 1929, Congress considered and rejected a bill "[t]o amend the Food and Drugs Act of June 30, 1906, by extending its provisions to tobacco and tobacco products." S. 1468, 71st Cong., 1st Sess., 1. See also 71 Cong. Rec. 2589 (1929) (remarks of Sen. Smoot). And, as the FDA admits, there is no evidence in the text of the FDCA or its legislative history that Congress in 1938 even considered the applicability of the Act to tobacco products. See Brief for Petitioners 22, n. 4. Given the economic and political significance of the tobacco industry at the time, it is extremely unlikely that Congress could have intended to place tobacco within the ambit of the FDCA absent any discussion of the matter. Of course, whether the Congress that enacted the FDCA specifically intended the Act to cover tobacco products is not determinative; "it is ultimately the provisions of our laws rather than the principal concerns of our legislators by which we are governed." *Oncale* v. *Sundowner Offshore Services, Inc.*, 523 U. S. 75, 79 (1998); see also *TVA* v. *Hill*, 437 U. S. 153, 185 (1978) ("It is not for us to speculate, much less act, on whether Congress would have altered its stance had the specific events of this case been anticipated"). Nonetheless, this intent is certainly relevant to understanding the basis for the FDA's representations to Congress and the background against which Congress enacted subsequent tobacco-specific legislation.

Moreover, before enacting the FCLAA in 1965, Congress considered and rejected several proposals to give the FDA the authority to regulate tobacco. In April 1963, Representative Udall introduced a bill "[t]o amend the Federal Food, Drug, and Cosmetic Act so as to make that Act applicable to smoking products." H. R. 5973, 88th Cong., 1st Sess., 1. Two months later, Senator Moss introduced

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an identical bill in the Senate. S. 1682, 88th Cong., 1st Sess. (1963). In discussing his proposal on the Senate floor, Senator Moss explained that "this amendment simply places smoking products under FDA jurisdiction, along with foods, drugs, and cosmetics." 109 Cong. Rec. 10322 (1963). In December 1963, Representative Rhodes introduced another bill that would have amended the FDCA "by striking out 'food, drug, device, or cosmetic, each place where it appears therein and inserting in lieu thereof 'food, drug, device, cosmetic, or smoking product.'" H. R. 9512, 88th Cong., 1st Sess., §3 (1963). And in January 1965, five months before passage of the FCLAA, Representative Udall again introduced a bill to amend the FDCA "to make that Act applicable to smoking products." H. R. 2248, 89th Cong., 1st Sess., 1. None of these proposals became law.

Congress ultimately decided in 1965 to subject tobacco products to the less extensive regulatory scheme of the FCLAA, which created a "comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health." Pub. L. 89–92, §2, 79 Stat. 282. The FCLAA rejected any regulation of advertising, but it required the warning, "Caution: Cigarette Smoking May Be Hazardous to Your Health," to appear on all cigarette packages. *Id.*, §4, 79 Stat. 283. In the Act's "Declaration of Policy," Congress stated that its objective was to balance the goals of ensuring that "the public may be adequately informed that cigarette smoking may be hazardous to health" and protecting "commerce and the national economy . . . to the maximum extent." *Id.*, §2, 79 Stat. 282 (codified at 15 U. S. C. §1331).

Not only did Congress reject the proposals to grant the FDA jurisdiction, but it explicitly preempted any other regulation of cigarette labeling: "No statement relating to smoking and health, other than the statement required by

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. . . this Act, shall be required on any cigarette package." *Id.*, §5(a), 79 Stat. 283. The regulation of product labeling, however, is an integral aspect of the FDCA, both as it existed in 1965 and today. The labeling requirements currently imposed by the FDCA, which are essentially identical to those in force in 1965, require the FDA to regulate the labeling of drugs and devices to protect the safety of consumers. See 21 U. S. C. §352; 21 U. S. C. §352 (1964 ed. and Supp. IV). As discussed earlier, the Act requires that all products bear "adequate directions for use . . . as are necessary for the protection of users," 21 U. S. C. §352(f)(1); 21 U. S. C. §352(f)(1) (1964 ed.); requires that all products provide "adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health," 21 U. S. C. §352(f)(2); 21 U. S. C. §352(f)(2) (1964 ed.); and deems a product misbranded "[i]f it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof," 21 U. S. C. §352(j); 21 U. S. C. §352(j) (1964 ed.). In this sense, the FCLAA was—and remains—incompatible with FDA regulation of tobacco products. This is not to say that the FCLAA's preemption provision by itself necessarily foreclosed FDA jurisdiction. See *Cipollone v. Liggett Group, Inc.*, 505 U. S., at 518–519. But it is an important factor in assessing whether Congress ratified the agency's position—that is, whether Congress adopted a regulatory approach to the problem of tobacco and health that contemplated no role for the FDA.

Further, the FCLAA evidences Congress' intent to preclude *any* administrative agency from exercising significant policymaking authority on the subject of smoking and health. In addition to prohibiting any additional requirements for cigarette labeling, the FCLAA provided that "[n]o statement relating to smoking and health shall be required in the advertising of any cigarettes the packages

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of which are labeled in conformity with the provisions of this Act." Pub. L. 89–92, §5(b), 79 Stat. 283. Thus, in reaction to the FTC's attempt to regulate cigarette labeling and advertising, Congress enacted a statute reserving exclusive control over both subjects to itself.

Subsequent tobacco-specific legislation followed a similar pattern. By the FCLAA's own terms, the prohibition on any additional cigarette labeling or advertising regulations relating to smoking and health was to expire July 1, 1969. See §10, 79 Stat. 284. In anticipation of the provision's expiration, both the FCC and the FTC proposed rules governing the advertisement of cigarettes. See 34 Fed. Reg. 1959 (1969) (FCC proposed rule to "ban the broadcast of cigarette commercials by radio and television stations"), *id.*, at 7917 (FTC proposed rule requiring manufacturers to disclose on all packaging and in all print advertising "'that cigarette smoking is dangerous to health and may cause death from cancer, coronary heart disease, chronic bronchitis, pulmonary emphysema, and other diseases'"). After debating the proper role for administrative agencies in the regulation of tobacco, see generally Cigarette Labeling and Advertising—1969: Hearings before the House Committee on Interstate and Foreign Commerce, 91st Cong., 1st Sess., pt. 2 (1969), Congress amended the FCLAA by banning cigarette advertisements "on any medium of electronic communication subject to the jurisdiction of the Federal Communications Commission" and strengthening the warning required to appear on cigarette packages. Public Health Cigarette Smoking Act of 1969, Pub. L. 91–222, §§4, 6, 84 Stat. 88–89. Importantly, Congress extended indefinitely the prohibition on any other regulation of cigarette labeling with respect to smoking and health (again despite the importance of labeling regulation under the FDCA). §5(a), 84 Stat. 88 (codified at 15 U. S. C. §1334(a)). Moreover, it expressly forbade the FTC from taking any action on its

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pending rule until July 1, 1971, and it required the FTC, if it decided to proceed with its rule thereafter, to notify Congress at least six months in advance of the rule's becoming effective. §7(a), 84 Stat. 89. As the chairman of the House committee in which the bill originated stated, "the Congress—the body elected by the people—must make the policy determinations involved in this legislation—and not some agency made up of appointed officials." 116 Cong. Rec. 7920 (1970) (remarks of Rep. Staggers).

Four years later, after Congress had transferred the authority to regulate substances covered by the Hazardous Substances Act (HSA) from the FDA to the Consumer Products Safety Commission (CPSC), the American Public Health Association, joined by Senator Moss, petitioned the CPSC to regulate cigarettes yielding more than 21 milligrams of tar. See *Action on Smoking and Health* v. *Harris*, 655 F. 3d 236, 241 (CADC 1980); R. Kluger, Ashes to Ashes 375–376 (1996). After the CPSC determined that it lacked authority under the HSA to regulate cigarettes, a District Court held that the Act did, in fact, grant the CPSC such jurisdiction and ordered it to reexamine the petition. See *American Public Health Association* v. *Consumer Product Safety Commission*, [1972–1975 Transfer Binder] CCH Consumer Prod. Safety Guide ¶75,081 (DC 1975), vacated as moot, No. 75–1863 (CADC 1976). Before the CPSC could take any action, however, Congress mooted the issue by adopting legislation that eliminated the agency's authority to regulate "tobacco and tobacco products." Consumer Product Safety Commission Improvements Act of 1976, Pub. L. 94–284, §3(c), 90 Stat. 503 (codified at 15 U. S. C. §1261(f)(2)). Senator Moss acknowledged that the "legislation, in effect, reverse[d]" the District Court's decision, 121 Cong. Rec. 23563 (1975), and the FDA later observed that the episode was "particularly" "indicative of the policy of Congress to limit the regulatory authority over cigarettes by Federal Agencies," Letter to

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Action on Smoking and Health (ASH) Executive Director Banzhaf from FDA Commissioner Goyan (Nov. 25, 1980), App. 59. A separate statement in the Senate Report underscored that the legislation's purpose was to "unmistakably reaffirm the clear mandate of the Congress that the basic regulation of tobacco and tobacco products is governed by the legislation dealing with the subject, . . . and that any further regulation in this sensitive and complex area must be reserved for specific Congressional action." S. Rep. No. 94–251, p. 43 (1975) (additional views of Sens. Hartke, Hollings, Ford, Stevens, and Beall).

Meanwhile, the FDA continued to maintain that it lacked jurisdiction under the FDCA to regulate tobacco products as customarily marketed. In 1972, FDA Commissioner Edwards testified before Congress that "cigarettes recommended for smoking pleasure are beyond the Federal Food, Drug, and Cosmetic Act." 1972 Hearings 239, 242. He further stated that the FDA believed that the Public Health Cigarette Smoking Act "demonstrates that the regulation of cigarettes is to be the domain of Congress," and that "labeling or banning cigarettes is a step that can be take[n] only by the Congress. Any such move by FDA would be inconsistent with the clear congressional intent." *Ibid.*

In 1977, ASH filed a citizen petition requesting that the FDA regulate cigarettes, citing many of the same grounds that motivated the FDA's rulemaking here. See Citizen Petition, No. 77P–0185 (May 26, 1977), 10 Rec. in No. 97–1604 (CA4), Tab No. 22, pp. 1–10. ASH asserted that nicotine was highly addictive and had strong physiological effects on the body; that those effects were "intended" because consumers use tobacco products precisely to obtain those effects; and that tobacco causes thousands of premature deaths annually. *Ibid.* In denying ASH's petition, FDA Commissioner Kennedy stated that "[t]he interpretation of the Act by FDA consistently has been

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that cigarettes are not a drug unless health claims are made by the vendors." Letter to ASH Executive Director Banzhaf (Dec. 5, 1977), App. 47. After the matter proceeded to litigation, the FDA argued in its brief to the Court of Appeals that "cigarettes are not comprehended within the statutory definition of the term 'drug' absent objective evidence that vendors represent or intend that their products be used as a drug." Brief for Appellee in *Action on Smoking and Health* v. *Harris*, 655 F. 2d 236 (CADC 1980), 9 Rec. in No. 97–1604 (CA4), Tab No. 4, pp. 27–28. The FDA also contended that Congress had "long been aware that the FDA does not consider cigarettes to be within its regulatory authority in the absence of health claims made on behalf of the manufacturer or vendor," and that, because "Congress has never acted to disturb the agency's interpretation," it had "acquiesced in the FDA's interpretation of the statutory limits on its authority to regulate cigarettes." *Id.*, at 23, 27, n. 23. The Court of Appeals upheld the FDA's position, concluding that "[i]f the statute requires expansion, that is the job of Congress." *Action on Smoking and Health* v. *Harris*, 655 F. 2d, at 243. In 1980, the FDA also denied a request by ASH to commence rulemaking proceedings to establish the agency's jurisdiction to regulate cigarettes as devices. See Letter to ASH Executive Director Banzhaf from FDA Commissioner Goyan (Nov. 25, 1980), App. 50–51. The agency stated that "[i]nsofar as rulemaking would relate to cigarettes or attached filters as customarily marketed, we have concluded that FDA has no jurisdiction under section 201(h) of the Act [21 U. S. C. §321(h)]." *Id.*, at 67.

In 1983, Congress again considered legislation on the subject of smoking and health. HHS Assistant Secretary Brandt testified that, in addition to being "a major cause of cancer," smoking is a "major cause of heart disease" and other serious illnesses, and can result in "unfavorable pregnancy outcomes." 1983 House Hearings 19–20. He

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also stated that it was "well-established that cigarette smoking is a drug dependence, and that smoking is addictive for many people." *Id.*, at 20. Nonetheless, Assistant Secretary Brandt maintained that "the issue of regulation of tobacco . . . is something that Congress has reserved to itself, and we do not within the Department have the authority to regulate nor are we seeking such authority." *Id.*, at 74. He also testified before the Senate, stating that, despite the evidence of tobacco's health effects and addictiveness, the Department's view was that "Congress has assumed the responsibility of regulating . . . cigarettes." Smoking Prevention and Education Act: Hearings on S. 772 before the Senate Committee on Labor and Human Resources, 98th Cong., 1st Sess., 56 (1983) (hereinafter 1983 Senate Hearings).

Against this backdrop, Congress enacted three additional tobacco-specific statutes over the next four years that incrementally expanded its regulatory scheme for tobacco products. In 1983, Congress adopted the Alcohol and Drug Abuse Amendments, Pub. L. 98–24, 97 Stat. 175 (codified at 42 U. S. C. §290aa *et seq.*), which require the Secretary of HHS to report to Congress every three years on the "addictive property of tobacco" and to include recommendations for action that the Secretary may deem appropriate. A year later, Congress enacted the Comprehensive Smoking Education Act, Pub. L. 98–474, 98 Stat. 2200, which amended the FCLAA by again modifying the prescribed warning. Notably, during debate on the Senate floor, Senator Hawkins argued that the Act was necessary in part because "[u]nder the Food, Drug and Cosmetic Act, the Congress exempted tobacco products." 130 Cong. Rec. 26953 (1984). And in 1986, Congress enacted the Comprehensive Smokeless Tobacco Health Education Act of 1986 (CSTHEA), Pub. L. 99–252, 100 Stat. 30 (codified at 15 U. S. C. §4401 *et seq.*), which essentially extended the regulatory provisions of the FCLAA to smokeless tobacco

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products. Like the FCLAA, the CSTHEA provided that "[n]o statement relating to the use of smokeless tobacco products and health, other than the statements required by [the Act], shall be required by any Federal agency to appear on any package . . . of a smokeless tobacco product." §7(a), 100 Stat. 34 (codified at 15 U. S. C. §4406(a)). Thus, as with cigarettes, Congress reserved for itself an aspect of smokeless tobacco regulation that is particularly important to the FDCA's regulatory scheme.

In 1988, the Surgeon General released a report summarizing the abundant scientific literature demonstrating that "[c]igarettes and other forms of tobacco are addicting," and that "nicotine is psychoactive" and "causes physical dependence characterized by a withdrawal syndrome that usually accompanies nicotine abstinence." 1988 Surgeon General's Report 14. The report further concluded that the "pharmacologic and behavioral processes that determine tobacco addiction are similar to those that determine addiction to drugs such as heroin and cocaine." *Id.*, at 15. In the same year, FDA Commissioner Young stated before Congress that "it doesn't look like it is possible to regulate [tobacco] under the Food, Drug and Cosmetic Act even though smoking, I think, has been widely recognized as being harmful to human health." Rural Development, Agriculture, and Related Agencies Appropriations for 1989: Hearings before a Subcommittee of the House Committee on Appropriations, 100th Cong., 2d Sess., 409 (1988). At the same hearing, the FDA's General Counsel testified that "what is fairly important in FDA law is whether a product has a therapeutic purpose," and "[c]igarettes themselves are not used for a therapeutic purpose as that concept is ordinarily understood." *Id.*, at 410. Between 1987 and 1989, Congress considered three more bills that would have amended the FDCA to grant the FDA jurisdiction to regulate tobacco products. See H. R. 3294, 100th Cong., 1st Sess. (1987); H. R. 1494,

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101st Cong., 1st Sess. (1989); S. 769, 101st Cong., 1st Sess. (1989). As before, Congress rejected the proposals. In 1992, Congress instead adopted the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act, Pub. L. 102–321, §202, 106 Stat. 394 (codified at 42 U. S. C. §300x *et seq.*), which creates incentives for States to regulate the retail sale of tobacco products by making States' receipt of certain block grants contingent on their prohibiting the sale of tobacco products to minors.

Taken together, these actions by Congress over the past 35 years preclude an interpretation of the FDCA that grants the FDA jurisdiction to regulate tobacco products. We do not rely on Congress' failure to act—its consideration and rejection of bills that would have given the FDA this authority—in reaching this conclusion. Indeed, this is not a case of simple inaction by Congress that purportedly represents its acquiescence in an agency's position. To the contrary, Congress has enacted several statutes addressing the particular subject of tobacco and health, creating a distinct regulatory scheme for cigarettes and smokeless tobacco. In doing so, Congress has been aware of tobacco's health hazards and its pharmacological effects. It has also enacted this legislation against the background of the FDA repeatedly and consistently asserting that it lacks jurisdiction under the FDCA to regulate tobacco products as customarily marketed. Further, Congress has persistently acted to preclude a meaningful role for *any* administrative agency in making policy on the subject of tobacco and health. Moreover, the substance of Congress' regulatory scheme is, in an important respect, incompatible with FDA jurisdiction. Although the supervision of product labeling to protect consumer health is a substantial component of the FDA's regulation of drugs and devices, see 21 U. S. C. §352 (1994 ed. and Supp. III), the FCLAA and the CSTHEA explicitly prohibit any federal agency from imposing any health-related labeling requirements on

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cigarettes or smokeless tobacco products, see 15 U. S C. §§1334(a), 4406(a).

Under these circumstances, it is clear that Congress' tobacco-specific legislation has effectively ratified the FDA's previous position that it lacks jurisdiction to regulate tobacco. As in *Bob Jones Univ.* v. *United States,* 461 U. S. 574 (1983), "[i]t is hardly conceivable that Congress—and in this setting, any Member of Congress—was not abundantly aware of what was going on." *Id.,* at 600–601. Congress has affirmatively acted to address the issue of tobacco and health, relying on the representations of the FDA that it had no authority to regulate tobacco. It has created a distinct scheme to regulate the sale of tobacco products, focused on labeling and advertising, and premised on the belief that the FDA lacks such jurisdiction under the FDCA. As a result, Congress' tobacco-specific statutes preclude the FDA from regulating tobacco products as customarily marketed.

Although the dissent takes issue with our discussion of the FDA's change in position, *post,* at 26–29, our conclusion does not rely on the fact that the FDA's assertion of jurisdiction represents a sharp break with its prior interpretation of the FDCA. Certainly, an agency's initial interpretation of a statute that it is charged with administering is not "carved in stone." *Chevron,* 467 U. S., at 863; see also *Smiley* v. *Citibank (South Dakota), N. A.,* 517 U. S. 735, 742 (1996). As we recognized in *Motor Vehicle Mfrs. Assn. of United States, Inc.* v. *State Farm Mut. Automobile Ins. Co.,* 463 U. S. 29 (1983), agencies "must be given ample latitude to 'adapt their rules and policies to the demands of changing circumstances.'" *Id.,* at 42 (quoting *Permian Basin Area Rate Cases,* 390 U. S. 747, 784 (1968)). The consistency of the FDA's prior position is significant in this case for a different reason: it provides important context to Congress' enactment of its tobacco-specific legislation. When the FDA repeatedly informed Congress

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that the FDCA does not grant it the authority to regulate tobacco products, its statements were consistent with the agency's unwavering position since its inception, and with the position that its predecessor agency had first taken in 1914. Although not crucial, the consistency of the FDA's prior position bolsters the conclusion that when Congress created a distinct regulatory scheme addressing the subject of tobacco and health, it understood that the FDA is without jurisdiction to regulate tobacco products and ratified that position.

The dissent also argues that the proper inference to be drawn from Congress' tobacco-specific legislation is "critically ambivalent." *Post*, at 22. We disagree. In that series of statutes, Congress crafted a specific legislative response to the problem of tobacco and health, and it did so with the understanding, based on repeated assertions by the FDA, that the agency has no authority under the FDCA to regulate tobacco products. Moreover, Congress expressly preempted any other regulation of the labeling of tobacco products concerning their health consequences, even though the oversight of labeling is central to the FDCA's regulatory scheme. And in addressing the subject, Congress consistently evidenced its intent to preclude any federal agency from exercising significant policymaking authority in the area. Under these circumstances, we believe the appropriate inference—that Congress intended to ratify the FDA's prior position that it lacks jurisdiction—is unmistakable.

The dissent alternatively argues that, even if Congress' subsequent tobacco-specific legislation did, in fact, ratify the FDA's position, that position was merely a contingent disavowal of jurisdiction. Specifically, the dissent contends that "the FDA's traditional view was largely premised on a perceived inability to prove the necessary statutory 'intent' requirement." *Post*, at 30. A fair reading of the FDA's representations prior to 1995, however, demon-

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strates that the agency's position was essentially unconditional. See, *e.g.*, 1972 Hearings 239, 242 (statement of Commissioner Edwards) ("[R]egulation of cigarettes is to be the domain of Congress," and "[a]ny such move by FDA would be inconsistent with the clear congressional intent"); 1983 House Hearings 74 (statement of Assistant Secretary Brandt) ("[T]he issue of regulation of tobacco . . . is something that Congress has reserved to itself"); 1983 Senate Hearings 56 (statement of Assistant Secretary Brandt) ("Congress has assumed the responsibility of regulating . . . cigarettes"); Brief for Appellee in *Action on Smoking and Health* v. *Harris*, 655 F. 2d 236 (CADC 1980), 9 Rec. in No. 97–1604 (CA4), Tab No. 4, pp. 27, n. 23 (because "Congress has never acted to disturb the agency's interpretation," it "acquiesced in the FDA's interpretation"). To the extent the agency's position could be characterized as equivocal, it was only with respect to the well-established exception of when the manufacturer makes express claims of therapeutic benefit. See, *e.g.*, 1965 Hearings 193 (statement of Deputy Commissioner Rankin) ("The Food and Drug Administration has no jurisdiction under the Food, Drug, and Cosmetic Act over tobacco, unless it bears drug claims"); Letter to ASH Executive Director Banzhaf from FDA Commissioner Kennedy (Dec. 5, 1977), App. 47 ("The interpretation of the Act by FDA consistently has been that cigarettes are not a drug unless health claims are made by the vendors"); Letter to ASH Executive Director Banzhaf from FDA Commissioner Goyan (Nov. 25, 1980), App. 67 ("Insofar as rulemaking would relate to cigarettes or attached filters as customarily marketed, we have concluded that FDA has no jurisdiction"). Thus, what Congress ratified was the FDA's plain and resolute position that the FDCA gives the agency no authority to regulate tobacco products as customarily marketed.

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Finally, our inquiry into whether Congress has directly spoken to the precise question at issue is shaped, at least in some measure, by the nature of the question presented. Deference under *Chevron* to an agency's construction of a statute that it administers is premised on the theory that a statute's ambiguity constitutes an implicit delegation from Congress to the agency to fill in the statutory gaps. See *Chevron*, 467 U. S., at 844. In extraordinary cases, however, there may be reason to hesitate before concluding that Congress has intended such an implicit delegation. Cf. Breyer, Judicial Review of Questions of Law and Policy, 38 Admin. L. Rev. 363, 370 (1986) ("A court may also ask whether the legal question is an important one. Congress is more likely to have focused upon, and answered, major questions, while leaving interstitial matters to answer themselves in the course of the statute's daily administration").

This is hardly an ordinary case. Contrary to its representations to Congress since 1914, the FDA has now asserted jurisdiction to regulate an industry constituting a significant portion of the American economy. In fact, the FDA contends that, were it to determine that tobacco products provide no "reasonable assurance of safety," it would have the authority to ban cigarettes and smokeless tobacco entirely. See Brief for Petitioners 35–36; Reply Brief for Petitioners 14. Owing to its unique place in American history and society, tobacco has its own unique political history. Congress, for better or for worse, has created a distinct regulatory scheme for tobacco products, squarely rejected proposals to give the FDA jurisdiction over tobacco, and repeatedly acted to preclude any agency from exercising significant policymaking authority in the area. Given this history and the breadth of the authority that the FDA has asserted, we are obliged to defer not to

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the agency's expansive construction of the statute, but to Congress' consistent judgment to deny the FDA this power.

Our decision in *MCI Telecommunications Corp.* v. *American Telephone & Telegraph Co.*, 512 U. S. 218 (1994), is instructive. That case involved the proper construction of the term "modify" in §203(b) of the Communications Act of 1934. The FCC contended that, because the Act gave it the discretion to "modify any requirement" imposed under the statute, it therefore possessed the authority to render voluntary the otherwise mandatory requirement that long distance carriers file their rates. *Id.*, at 225. We rejected the FCC's construction, finding "not the slightest doubt" that Congress had directly spoken to the question. *Id.*, at 228. In reasoning even more apt here, we concluded that "[i]t is highly unlikely that Congress would leave the determination of whether an industry will be entirely, or even substantially, rate-regulated to agency discretion—and even more unlikely that it would achieve that through such a subtle device as permission to 'modify' rate-filing requirements." *Id.*, at 231.

As in *MCI*, we are confident that Congress could not have intended to delegate a decision of such economic and political significance to an agency in so cryptic a fashion. To find that the FDA has the authority to regulate tobacco products, one must not only adopt an extremely strained understanding of "safety" as it is used throughout the Act—a concept central to the FDCA's regulatory scheme—but also ignore the plain implication of Congress' subsequent tobacco-specific legislation. It is therefore clear, based on the FDCA's overall regulatory scheme and the subsequent tobacco legislation, that Congress has directly spoken to the question at issue and precluded the FDA from regulating tobacco products.

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* * *

By no means do we question the seriousness of the problem that the FDA has sought to address. The agency has amply demonstrated that tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States. Nonetheless, no matter how "important, conspicuous, and controversial" the issue, and regardless of how likely the public is to hold the Executive Branch politically accountable, *post*, at 31, an administrative agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress. And "'[i]n our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop.'" *United States* v. *Article of Drug ... Bacto-Unidisk*, 394 U. S. 784, 800 (1969) (quoting *62 Cases of Jam* v. *United States*, 340 U. S. 593, 600 (1951)). Reading the FDCA as a whole, as well as in conjunction with Congress' subsequent tobacco-specific legislation, it is plain that Congress has not given the FDA the authority that it seeks to exercise here. For these reasons, the judgment of the Court of Appeals for the Fourth Circuit is affirmed.

It is so ordered.

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SUPREME COURT OF THE UNITED STATES

No. 98–1152

FOOD AND DRUG ADMINISTRATION, ET AL., PETITIONERS *v.* BROWN & WILLIAMSON TOBACCO CORPORATION ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

[March 21, 2000]

JUSTICE BREYER, with whom JUSTICE STEVENS, JUSTICE SOUTER, and JUSTICE GINSBURG join, dissenting.

The Food and Drug Administration (FDA) has the authority to regulate "articles (other than food) intended to affect the structure or any function of the body . . . ." Federal Food, Drug and Cosmetic Act (FDCA), 21 U. S. C. §321(g)(1)(C). Unlike the majority, I believe that tobacco products fit within this statutory language.

In its own interpretation, the majority nowhere denies the following two salient points. First, tobacco products (including cigarettes) fall within the scope of this statutory definition, read literally. Cigarettes achieve their mood-stabilizing effects through the interaction of the chemical nicotine and the cells of the central nervous system. Both cigarette manufacturers and smokers alike know of, and desire, that chemically induced result. Hence, cigarettes are "intended to affect" the body's "structure" and "function," in the literal sense of these words.

Second, the statute's basic purpose—the protection of public health—supports the inclusion of cigarettes within its scope. See *United States* v. *Article of Drug ... Bacto-Unidisk*, 394 U. S. 784, 798 (1969) (FDCA "is to be given *a liberal construction consistent with [its] overriding purpose to protect the public health*" (emphasis added)).

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Unregulated tobacco use causes "[m]ore than 400,000 people [to] die each year from tobacco-related illnesses, such as cancer, respiratory illnesses, and heart disease." 61 Fed. Reg. 44398 (1996). Indeed, tobacco products kill more people in this country every year "than . . . AIDS, car accidents, alcohol, homicides, illegal drugs, suicides, and fires, *combined*." *Ibid.* (emphasis added).

Despite the FDCA's literal language and general purpose (both of which support the FDA's finding that cigarettes come within its statutory authority), the majority nonetheless reads the statute as *excluding* tobacco products for two basic reasons:

> (1) the FDCA does not "fit" the case of tobacco because the statute requires the FDA to prohibit dangerous drugs or devices (like cigarettes) outright, and the agency concedes that simply banning the sale of cigarettes is not a proper remedy, *ante*, at 19–20; and
>
> (2) Congress has enacted other statutes, which, when viewed in light of the FDA's long history of denying tobacco-related jurisdiction and considered together with Congress' failure explicitly to grant the agency tobacco-specific authority, demonstrate that Congress did not intend for the FDA to exercise jurisdiction over tobacco, *ante*, at 33–34.

In my view, neither of these propositions is valid. Rather, the FDCA does not significantly limit the FDA's remedial alternatives. See *infra*, at 14–21. And the later statutes do not tell the FDA it cannot exercise jurisdiction, but simply leave FDA jurisdictional law where Congress found it. See *infra*, at 21–26; cf. Food and Drug Administration Modernization Act of 1997, 111 Stat. 2380 (codified at note following 21 U. S. C. §321 (1994 ed., Supp. III)) (statute "shall" *not* "be construed to affect the question of whether" the FDA "has any authority to regulate any tobacco product").

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The bulk of the opinion that follows will explain the basis for these latter conclusions. In short, I believe that the most important indicia of statutory meaning—language and purpose—along with the FDCA's legislative history (described briefly in Part I) are sufficient to establish that the FDA has authority to regulate tobacco. The statute-specific arguments against jurisdiction that the tobacco companies and the majority rely upon (discussed in Part II) are based on erroneous assumptions and, thus, do not defeat the jurisdiction-supporting thrust of the FDCA's language and purpose. The inferences that the majority draws from later legislative history are not persuasive, since (as I point out in Part III) one can just as easily infer from the later laws that Congress did not intend to affect the FDA's tobacco-related authority at all. And the fact that the FDA changed its mind about the scope of its own jurisdiction is legally insignificant because (as Part IV establishes) the agency's reasons for changing course are fully justified. Finally, as I explain in Part V, the degree of accountability that likely will attach to the FDA's action in this case should alleviate any concern that Congress, rather than an administrative agency, ought to make this important regulatory decision.

I

Before 1938, the federal Pure Food and Drug Act contained only two jurisdictional definitions of "drug":

> "[1] medicines and preparations recognized in the United States Pharmacopoeia or National Formulary . . . and [2] any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease." Act of June 30, 1906, ch. 3915, §6, 34 Stat. 769.

In 1938, Congress added a third definition, relevant here:

> "(3) articles (other than food) intended to affect the

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structure or any function of the body . . . ." Act of June 25, 1938, ch. 675, §201(g), 52 Stat. 1041 (codified at 21 U. S. C. §321(g)(1)(C)).

It also added a similar definition in respect to a "device." See §201(h), 52 Stat. 1041 (codified at 21 U. S. C. §321(h)). As I have mentioned, the literal language of the third definition and the FDCA's general purpose both strongly support a projurisdiction reading of the statute. See *supra*, at 1–2.

The statute's history offers further support. The FDA drafted the new language, and it testified before Congress that the third definition would expand the FDCA's jurisdictional scope significantly. See Hearings on S. 1944 before a Subcommittee of the Senate Committee on Commerce, 73d Cong., 2d Sess., 15–16 (1933), reprinted in 1 FDA, Legislative History of the Federal Food, Drug, and Cosmetic Act and Its Amendments 107–108 (1979) (hereinafter Leg. Hist.). Indeed, "[t]he purpose" of the new definition was to "make possible the regulation of a great many products that have been found on the market that cannot be alleged to be treatments for diseased conditions." *Id.*, at 108. While the drafters focused specifically upon the need to give the FDA jurisdiction over "slenderizing" products such as "antifat remedies," *ibid.*, they were aware that, in doing so, they had created what was "admittedly an inclusive, a wide definition." *Id.*, at 107. And that broad language was included *deliberately*, so that jurisdiction could be had over "*all* substances and preparations, other than food, and *all* devices intended to affect the structure or any function of the body . . . ." *Ibid.* (emphasis added); see also Hearings on S. 2800 before the Senate Committee on Commerce, 73d Cong., 2d Sess. 516 (1934), reprinted in 2 Leg. Hist. 519 (statement of then-FDA Chief Walter Campbell acknowledging that "[t]his definition of 'drugs' is all-inclusive").

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After studying the FDCA's history, experts have written that the statute "is a purposefully broad delegation of discretionary powers by Congress," J. O'Reilly, 1 Food and Drug Administration §6.01, p. 6–1 (2d ed. 1995) (hereinafter O'Reilly), and that, in a sense, the FDCA "must be regarded as a *constitution*" that "establish[es] general principles" and "permit[s] implementation within broad parameters" so that the FDA can "implement these objectives through the most effective and efficient controls that can be devised." Hutt, Philosophy of Regulation Under the Federal Food, Drug and Cosmetic Act, 28 Food Drug Cosm. L. J. 177, 178–179 (1973) (emphasis added). This Court, too, has said that the

> "historical expansion of the definition of drug, and the creation of a parallel concept of devices, clearly show . . . that Congress fully intended that the Act's coverage be as broad as its literal language indicates—and equally clearly, broader than any strict medical definition might otherwise allow." *Bacto-Unidisk*, 394 U. S., at 798.

That Congress would grant the FDA such broad jurisdictional authority should surprise no one. In 1938, the President and much of Congress believed that federal administrative agencies needed broad authority and would exercise that authority wisely—a view embodied in much Second New Deal legislation. Cf. *Gray* v. *Powell*, 314 U. S. 402, 411–412 (1941) (Congress "could have legislated specifically" but decided "to delegate that function to those whose experience in a particular field gave promise of a better informed, more equitable" determination). Thus, at around the same time that it added the relevant language to the FDCA, Congress enacted laws granting other administrative agencies even broader powers to regulate much of the Nation's transportation and communication. See, *e.g.*, Civil Aeronautics Act of 1938, ch. 601, §401(d)(1), 52 Stat.

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advanced communications systems). After all, this Court has read more narrowly phrased statutes to grant what might have seemed even more unlikely assertions of agency jurisdiction. See, *e.g.*, *Permian Basin Area Rate Cases*, 390 U. S. 747, 774–777 (1968) (statutory authority to regulate interstate "transportation" of natural gas includes authority to regulate "prices" charged by field producers); *Phillips Petroleum Co.* v. *Wisconsin*, 347 U. S. 672, 677–684 (1954) (independent gas producer subject to regulation despite Natural Gas Act's express exemption of gathering and production facilities).

I shall not pursue these general matters further, for neither the companies nor the majority denies that the FDCA's literal language, its general purpose, and its particular legislative history favor the FDA's present jurisdictional view. Rather, they have made several specific arguments in support of one basic contention: even if the statutory delegation is broad, it is not broad *enough* to include tobacco. I now turn to each of those arguments.

II

A

The tobacco companies contend that the FDCA's words cannot possibly be read to mean what they literally say. The statute defines "device," for example, as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article . . . intended to affect the structure or any function of the body . . . ." 21 U. S. C. §321(h). Taken literally, this definition might include everything from room air conditioners to thermal pajamas. The companies argue that, to avoid such a result, the meaning of "drug" or "device" should be confined to *medical* or *therapeutic* products, narrowly defined. See Brief for Respondent United States Tobacco Co. 8–9.

The companies may well be right that the statute should

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not be read to cover room air conditioners and winter underwear. But I do not agree that we must accept their proposed limitation. For one thing, such a cramped reading contravenes the established purpose of the statutory language. See *Bacto-Unidisk*, 394 U. S., at 798 (third definition is "clearly, broader than any strict medical definition"); 1 Leg. Hist. 108 (definition covers products "that cannot be alleged to be treatments for diseased conditions"). For another, the companies' restriction would render the other two "drug" definitions superfluous. See 21 U. S. C. §§321(g)(1)(A), (g)(1)(B) (covering articles in the leading pharmacology compendia and those "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease").

Most importantly, the statute's language itself supplies a different, more suitable, limitation: that a "drug" must be a *chemical* agent. The FDCA's "device" definition states that an article which affects the structure or function of the body is a "device" only if it "does *not* achieve its primary intended purposes through chemical action within ... the body," and "is *not* dependent upon being metabolized for the achievement of its primary intended purposes." §321(h) (emphasis added). One can readily infer from this language that at least an article that *does* achieve its primary purpose through chemical action within the body and that *is* dependent upon being metabolized is a "drug," provided that it otherwise falls within the scope of the "drug" definition. And one need not hypothesize about air conditioners or thermal pajamas to recognize that the chemical nicotine, an important tobacco ingredient, meets this test.

Although I now oversimplify, the FDA has determined that once nicotine enters the body, the blood carries it almost immediately to the brain. See 61 Fed. Reg. 44698–44699 (1966). Nicotine then binds to receptors on the surface of brain cells, setting off a series of chemical reac-

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tions that alter one's mood and produce feelings of sedation and stimulation. See *id.*, at 44699, 44739. Nicotine also increases the number of nicotinic receptors on the brain's surface, and alters its normal electrical activity. See *id.*, at 44739. And nicotine stimulates the transmission of a natural chemical that "rewards" the body with pleasurable sensations (dopamine), causing nicotine addiction. See *id.*, at 44700, 44721–44722. The upshot is that nicotine stabilizes mood, suppresses appetite, tranquilizes, and satisfies a physical craving that nicotine itself has helped to create—all through chemical action within the body after being metabolized.

This physiology—and not simply smoker psychology—helps to explain why as many as 75% of adult smokers believe that smoking "reduce[s] nervous irritation," 60 Fed. Reg. 41579 (1995); why 73% of young people (10- to 22-year-olds) who begin smoking say they do so for "relaxation," 61 Fed. Reg. 44814 (1996); and why less than 3% of the 70% of smokers who want to quit each year succeed, *id.*, at 44704. That chemistry also helps to explain the Surgeon General's findings that smokers believe "smoking [makes them] feel better" and smoke more "in situations involving negative mood." *Id.*, at 44814. And, for present purposes, that chemistry demonstrates that nicotine affects the "structure" and "function" of the body in a manner that is quite similar to the effects of other regulated substances. See *id.*, at 44667 (FDA regulates Valium, NoDoz, weight-loss products). Indeed, addiction, sedation, stimulation, and weight loss are *precisely* the kinds of product effects that the FDA typically reviews and controls. And, since the nicotine in cigarettes plainly is not a "food," its chemical effects suffice to establish that it is as a "drug" (and the cigarette that delivers it a drug-delivery "device") for the purpose of the FDCA.

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B

The tobacco companies' principal definitional argument focuses upon the statutory word "intended." See 21 U. S. C. §321(g)(1)(C). The companies say that "intended" in this context is a term of art. See Brief for Respondent Brown & Williamson Tobacco Corp. 2. They assert that the statutory word "intended" means that the product's maker has made an *express claim* about the effect that its product will have on the body. *Ibid.* Indeed, according to the companies, the FDA's inability to prove that cigarette manufacturers make such claims is precisely why that agency historically has said it lacked the statutory power to regulate tobacco. See *id.*, at 19–20.

The FDCA, however, does not use the word "claimed"; it uses the word "intended." And the FDA long ago issued regulations that say the relevant "intent" can be shown not only by a manufacturer's "expressions," *but also* "by the circumstances surrounding the distribution of the article." 41 Fed. Reg. 6896 (1976) (codified at 21 CFR §801.4 (1999)); see also 41 Fed. Reg. 6896 (1976) ("objective intent" shown if "article is, with the knowledge [of its makers], offered and used" for a particular purpose). Thus, even in the absence of express claims, the FDA has regulated products that affect the body if the manufacturer wants, and knows, that consumers so use the product. See, *e.g.*, 60 Fed. Reg. 41527–41531 (1995) (describing agency's regulation of topical hormones, sunscreens, fluoride, tanning lamps, thyroid in food supplements, novelty condoms—all marketed without express claims); see also O'Reilly, Food and Drug Administration §13.04, at 13–15 ("Sometimes the very nature of the material makes it a drug . . .").

Courts ordinarily reverse an agency interpretation of this kind only if Congress has clearly answered the interpretive question or if the agency's interpretation is unreasonable. *Chevron U. S. A. Inc.* v. *Natural Resources Defense*

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Council, Inc., 467 U. S. 837, 842–843 (1984). The companies, in an effort to argue the former, point to language in the legislative history tying the word "intended" to a technical concept called "intended use." But nothing in Congress' discussion either of "intended" or "intended use" suggests that an express claim (which *often* shows intent) is *always* necessary. Indeed, the primary statement to which the companies direct our attention says only that a manufacturer can determine what kind of regulation applies—"food" or "drug"—because, "through his representations in connection with its sale, [the manufacturer] can determine" whether an article is to be used as a "food," as a "drug," or as "both." S. Rep. No. 361, 74th Cong., 1st Sess., 4 (1935), reprinted in 3 Leg. Hist. 696.

Nor is the FDA's "objective intent" interpretation unreasonable. It falls well within the established scope of the ordinary meaning of the word "intended." See *Agnew* v. *United States*, 165 U. S. 36, 53 (1897) (intent encompasses the known consequences of an act). And the companies acknowledge that the FDA can regulate a drug-like substance in the ordinary circumstance, *i.e.*, where the manufacturer makes an express claim, so it is not unreasonable to conclude that the agency retains such power where a product's effects on the body are so well known (say, like those of aspirin or calamine lotion), that there is no *need* for express representations because the product speaks for itself.

The companies also cannot deny that the evidence of their intent is sufficient to satisfy the statutory word "intended" as the FDA long has interpreted it. In the first place, there was once a time when they actually *did* make express advertising claims regarding tobacco's mood-stabilizing and weight-reducing properties—and historical representations can portend present expectations. In the late 1920's, for example, the American Tobacco Company urged weight-conscious smokers to "'Reach for a Lucky in-

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stead of a sweet.'" Kluger, Ashes to Ashes, at 77–78. The advertisements of RJ Reynolds (RJR) emphasized mood stability by depicting a pilot remarking that "'It Takes Steady Nerves To Fly the Mail At Night . . . . That's why I smoke Camels. And I smoke plenty!'" *Id.*, at 86. RJR also advertised the stimulating quality of cigarettes, stating in one instance that "'You get a Lift with a Camel,'" and, in another, that Camels are "'A Harmless Restoration of the Flow of Natural Body Energy.'" *Id.*, at 87. And claims of medical proof of mildness (and of other beneficial effects) once were commonplace. See, *e.g.*, *id.*, at 93 (Brown & Williamson advertised Kool-brand mentholated cigarettes as "a tonic to hot, tired throats"); *id.*, at 101, 131 (Phillip Morris contended that "[r]ecognized laboratory tests have conclusively proven the advantage of Phillip Morris"); *id.*, at 88 (RJR proclaimed "'For Digestion's sake, smoke Camels! . . . Camels make mealtime more pleasant—digestion is stimulated—alkalinity increased'"). Although in recent decades cigarette manufacturers have stopped making express health claims in their advertising, consumers have come to understand what the companies no longer need to express—that through chemical action cigarettes stabilize mood, sedate, stimulate, and help suppress appetite.

Second, even though the companies refused to acknowledge publicly (until only very recently) that the nicotine in cigarettes has chemically induced, and habit-forming, effects, see, *e.g.*, Regulation of Tobacco Products (Part 1): Hearings before the House Subcommittee on Health and the Environment, 103d Cong., 2d Sess., 628 (1994) (hereinafter 1994 Hearings) (heads of seven major tobacco companies testified under oath that they believed "nicotine is *not* addictive" (emphasis added)), the FDA recently has gained access to solid, documentary evidence proving that cigarette manufacturers have long *known* tobacco produces these effects within the body through the metabo-

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lizing of chemicals, and that they have long *wanted* their products to produce those effects in this way.

For example, in 1972, a tobacco-industry scientist explained that "'[s]moke is beyond question the most optimized vehicle of nicotine,'" and "'the cigarette is the most optimized dispenser of smoke.'" 61 Fed. Reg. 44856 (1996). That same scientist urged company executives to

> "'[t]hink of the cigarette pack as a storage container for a day's supply of nicotine. . . . Think of the cigarette as a dispenser for a dose unit of nicotine [and] [t]hink of a puff of smoke as a vehicle of nicotine.'" *Ibid.* (Philip Morris).

That same year, other tobacco industry researchers told their superiors that

> "'in different situations and at different dose levels, nicotine appears to act as a stimulant, depressant, tranquilizer, psychic energizer, appetite reducer, antifatigue agent, or energizer. . . . Therefore, [tobacco] products may, in a sense, compete with a variety of other products with certain types of drug action.'" *Id.*, at 44669 (RJR).

A draft report prepared by authorities at Philip Morris said that nicotine

> "'is a physiologically active, nitrogen containing substance [similar to] quinine, cocaine, atropine and morphine. [And] [w]hile each of these [other] substances can be used to affect human physiology, nicotine has a particularly broad range of influence.'" *Id.*, at 44668–44669.

And a 1980 manufacturer's study stated that

> "'the pharmacological response of smokers to nicotine is believed to be responsible for an individual's smoking behaviour, providing the motivation for and the

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degree of satisfaction required by the smoker.'" *Id.*, at 44936 (Brown & Williamson).

With such evidence, the FDA has more than sufficiently established that the companies "intend" their products to "affect" the body within the meaning of the FDCA.

C

The majority nonetheless reaches the "inescapable conclusion" that the language and structure of the FDCA as a whole "simply do not fit" the kind of public health problem that tobacco creates. *Ante*, at 20. That is because, in the majority's view, the FDCA requires the FDA to ban outright "dangerous" drugs or devices (such as cigarettes); yet, the FDA concedes that an immediate and total cigarette-sale ban is inappropriate. *Ibid.*

This argument is curious because it leads with similarly "inescapable" force to precisely the opposite conclusion, namely, that the FDA *does* have jurisdiction but that it must ban cigarettes. More importantly, the argument fails to take into account the fact that a statute interpreted as requiring the FDA to pick a more dangerous over a less dangerous remedy would be a perverse statute, *causing*, rather than preventing, unnecessary harm whenever a total ban is likely the more dangerous response. And one can at least imagine such circumstances.

Suppose, for example, that a commonly used, mildly addictive sleeping pill (or, say, a kind of popular contact lens), plainly within the FDA's jurisdiction, turned out to pose serious health risks for certain consumers. Suppose further that many of those addicted consumers would ignore an immediate total ban, turning to a potentially more dangerous black-market substitute, while a less draconian remedy (say, adequate notice) would wean them gradually away to a safer product. Would the FDCA still *force* the FDA to impose the more dangerous remedy? For the following reasons, I think not.

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First, the statute's language does not restrict the FDA's remedial powers in this way. The FDCA permits the FDA to regulate a "combination product"—*i.e.*, a "device" (such as a cigarette) that contains a "drug" (such as nicotine)—under its "device" provisions. 21 U. S. C. §353(g)(1). And the FDCA's "device" provisions explicitly grant the FDA wide remedial discretion. For example, where the FDA cannot "otherwise" obtain "reasonable assurance" of a device's "safety and effectiveness," the agency may restrict by regulation a product's "sale, distribution, or use" upon "*such . . . conditions as the Secretary may prescribe.*" §360j(e)(1) (emphasis added). And the statutory section that most clearly addresses the FDA's power to ban (entitled "Banned devices") says that, where a device presents "an unreasonable and substantial risk of illness or injury," the Secretary "*may*"—not *must*—"initiate a proceeding . . . to make such device a banned device." §360f(a) (emphasis added).

The Court points to other statutory subsections which it believes require the FDA to ban a drug or device entirely, even where an outright ban risks more harm than other regulatory responses. See *ante*, at 12–13. But the cited provisions do no such thing. It is true, as the majority contends, that "the FDCA requires the FDA to place all devices" in "one of three classifications" and that Class III devices require "premarket approval." *Ante*, at 12, 13. But it is not the case that the FDA *must* place cigarettes in Class III because tobacco itself "present[s] a potential unreasonable risk of illness or injury." 21 U. S. C. §360c(a)(1)(C). In fact, Class III applies *only* where *regulation* cannot otherwise "provide reasonable assurance of . . . safety." §§360c(a)(1)(A), 360c(a)(1)(B) (placing a device in Class I or Class II when regulation can provide that assurance). Thus, the statute plainly allows the FDA to consider the relative, overall "safety" of a device in light of its regulatory alternatives, and where the FDA has chosen

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the least dangerous path, *i.e.*, the safest path, then it can—and does—provide a "reasonable assurance" of "safety" within the meaning of the statute. A good football helmet provides a reasonable assurance of safety for the player even if the sport itself is still dangerous. And the safest regulatory choice by definition offers a "reasonable" assurance of safety in a world where the other alternatives are yet more dangerous.

In any event, it is not entirely clear from the statute's text that a Class III categorization would require the FDA affirmatively to *withdraw* from the market dangerous devices, such as cigarettes, which are already widely distributed. See, *e.g.*, §360f(a) (when a device presents an "unreasonable and substantial risk of illness or injury," the Secretary "may" make it "a banned device"); §360h(a) (when a device "presents an unreasonable risk of substantial harm to the public health," the Secretary "may" require "notification"); §360h(b) (when a defective device creates an "unreasonable risk" of harm, the Secretary "may" order "repair, replacement, or refund"); cf. O'Reilly, Food and Drug Administration §18.08, at 18-38 (point of Class III "premarket approval" is to allow "careful scientific review" of each "truly new" device "*before* it is exposed" to users (emphasis added)).

Noting that the FDCA requires banning a "misbranded" drug, the majority also points to 21 U. S. C. §352(j), which deems a drug or device "misbranded" if "it is dangerous to health when used" as "prescribed, recommended, or suggested in the labeling." See *ante*, at 12. In addition, the majority mentions §352(f)(1), which calls a drug or device "misbranded" unless "its labeling bears . . . adequate directions for use" as "are necessary for the protection of users." *Ibid.* But this "misbranding" language is not determinative, for it permits the FDA to conclude that a drug or device is *not* "dangerous to health" and that it *does* have "adequate" directions *when regulated so as to render*

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it as harmless as possible. And surely the agency can determine that a substance is comparatively "safe" (*not* "dangerous") whenever it would be *less* dangerous to make the product available (subject to regulatory requirements) than suddenly to withdraw it from the market. Any other interpretation risks substantial harm of the sort that my sleeping pill example illustrates. See *supra*, at 14. And nothing in the statute prevents the agency from adopting a view of "safety" that would avoid such harm. Indeed, the FDA already seems to have taken this position when permitting distribution of toxic drugs, such as poisons used for chemotherapy, that are dangerous for the user but are not deemed "dangerous to health" in the relevant sense. See 61 Fed. Reg. 44413 (1996).

The tobacco companies point to another statutory provision which says that if a device "would cause serious, adverse health consequences or death, the Secretary *shall* issue a cease distribution order. 21 U. S. C. §360h(e)(1) (emphasis added). But that word "shall" in this context cannot mean that the Secretary must resort to the recall remedy *whenever* a device would have serious, adverse health effects. Rather, that language must mean that the Secretary "shall issue" a cease distribution order in compliance with the section's procedural requirements *if* the Secretary chooses *in her discretion* to use that particular subsection's recall remedy. Otherwise, the subsection would trump and make meaningless the same section's provision of other lesser remedies such as simple "notice" (which the Secretary similarly can impose if, but only if, she finds that the device "presents an unreasonable risk of substantial harm to the public"). §360h(a)(1). And reading the statute to compel the FDA to "recall" every dangerous device likewise would conflict with that same subsection's statement that the recall remedy "shall be *in addition to* [the other] remedies provided" in the statute. §360h(e)(3) (emphasis added).

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The statute's language, then, permits the agency to choose remedies consistent with its basic purpose—the overall protection of public health.

The second reason the FDCA does not require the FDA to select the more dangerous remedy, see *supra*, at 14, is that, despite the majority's assertions to the contrary, the statute does not distinguish among the kinds of health effects that the agency may take into account when assessing safety. The Court insists that the statute only permits the agency to take into account the health risks and benefits of the "*product itself*" as used by individual consumers, *ante*, at 17, and, thus, that the FDA is prohibited from considering that a ban on smoking would lead many smokers to suffer severe withdrawal symptoms or to buy possibly stronger, more dangerous, black market cigarettes—considerations that the majority calls "the aggregate health effects of alternative administrative actions." *Ibid.* But the FDCA expressly *permits* the FDA to take account of comparative safety in precisely this manner. See, *e.g.*, 21 U. S. C. §360h(e)(2)(B)(i)(II) (no device recall if "risk of recal[l]" presents "a greater health risk than" no recall); §360h(a) (notification "unless" notification "would present a greater danger" than "no such notification").

Moreover, one cannot distinguish in this context between a "specific" health risk incurred by an individual and an "aggregate" risk to a group. *All* relevant risk is, at bottom, risk to an individual; *all* relevant risk attaches to "the product itself"; and *all* relevant risk is "aggregate" in the sense that the agency aggregates health effects in order to determine risk to the individual consumer. If unregulated smoking will kill 4 individuals out of a typical group of 1,000 people, if regulated smoking will kill 1 out of 1,000, and if a smoking ban (because of the black market) will kill 2 out of 1,000; then these three possibilities means that in each group four, one, and two individuals, on average, will die respectively. And the risk to each

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individual consumer is 4/1000, 1/1000, and 2/1000 respectively. A "specific" risk to an individual consumer and "aggregate" risks are two sides of the same coin; each calls attention to the same set of facts. While there may be a theoretical distinction between the risk of the product itself and the risk related to the presence or absence of an intervening voluntary act (*e.g.*, the search for a replacement on the black market), the majority does not rely upon any such distinction, and the FDA's history of regulating "replacement" drugs such as methadone shows that it has long taken likely actual alternative consumer behavior into account.

I concede that, as a matter of logic, one could consider the FDA's "safety" evaluation to be different from its choice of remedies. But to read the statute to forbid the agency from taking account of the realities of consumer behavior either in assessing safety or in choosing a remedy could increase the risks of harm—doubling the risk of death to each "individual user" in my example above. Why would Congress insist that the FDA ignore such realities, even if the consequent harm would occur only unusually, say, where the FDA evaluates a product (a sleeping pill; a cigarette; a contact lens) that is already on the market, potentially habit forming, or popular? I can find no satisfactory answer to this question. And that, I imagine, is why the statute itself says nothing about any of the distinctions that the Court has tried to draw. See 21 U. S. C. §360c(a)(2) (instructing FDA to determine the safety and effectiveness of a "device" in part by weighing "*any* probable benefit to health . . . against *any* probable risk of injury or illness . . .") (emphasis added).

Third, experience counsels against an overly rigid interpretation of the FDCA that is divorced from the statute's overall health-protecting purposes. A different set of words, added to the FDCA in 1958 by the Delaney Amendment, provides that "no [food] additive shall be deemed to

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be safe if it is found [after appropriate tests] to induce cancer in man or animal." §348(c)(3). The FDA once interpreted this language as requiring it to ban any food additive, no matter how small the amount, that appeared in any food product if that additive was ever found to induce cancer in any animal, no matter how large a dose needed to induce the appearance of a single carcinogenic cell. See H. R. Rep. No. 95–658, p. 7 (1977) (discussing agency's view). The FDA believed that the statute's ban mandate was absolute and prevented it from establishing a level of "safe use" or even to judge whether "the benefits of continued use outweigh the risks involved." *Id.*, at 5. This interpretation—which in principle could have required the ban of everything from herbal teas to mushrooms—actually led the FDA to ban saccharine, see 42 Fed. Reg. 19996 (1977), though this extremely controversial regulatory response never took effect because Congress enacted, and has continually renewed, a law postponing the ban. See Saccharin Study and Labeling Act, Pub. L. 95–203, §3, 91 Stat. 1452; *e.g.*, Pub. L. 102–142, Tit. VI, 105 Stat. 910.

The Court's interpretation of the statutory language before us risks Delaney-type consequences with even less linguistic reason. Even worse, the view the Court advances undermines the FDCA's overall health-protecting purpose by placing the FDA in the strange dilemma of either banning completely a potentially dangerous drug or device or doing nothing at all. Saying that I have misunderstood its conclusion, the majority maintains that the FDA "may clearly regulate many 'dangerous' products without banning them." *Ante*, at 19. But it then adds that the FDA *must* ban—rather than otherwise regulate—a drug or device that "cannot be used safely for any therapeutic purpose." *Ibid.* If I misunderstand, it is only because this linchpin of the majority's conclusion remains unexplained. *Why* must a widely-used but unsafe device

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be withdrawn from the market when that particular remedy threatens the health of many and is thus more dangerous than another regulatory response? It is, indeed, a perverse interpretation that reads the FDCA to require the ban of a device that has no "safe" therapeutic purpose where a ban is the most dangerous remedial alternative.

In my view, where linguistically permissible, we should interpret the FDCA in light of Congress' overall desire to protect health. That purpose requires a flexible interpretation that both permits the FDA to take into account the realities of human behavior and allows it, in appropriate cases, to choose from its arsenal of statutory remedies. A statute so interpreted easily "fit[s]" this, and other, drug- and device-related health problems.

III

In the majority's view, laws enacted since 1965 require us to deny jurisdiction, whatever the FDCA might mean in their absence. But why? Do those laws contain language barring FDA jurisdiction? The majority must concede that they do not. Do they contain provisions that are inconsistent with the FDA's exercise of jurisdiction? With one exception, see *infra*, at 24, the majority points to no such provision. Do they somehow repeal the principles of law (discussed in Part II, *supra*) that otherwise would lead to the conclusion that the FDA has jurisdiction in this area? The companies themselves deny making any such claim. See Tr. of Oral Arg. 27 (denying reliance on doctrine of "partial repeal"). Perhaps the later laws "shape" and "focus" what the 1938 Congress meant a generation earlier. *Ante*, at 20. But this Court has warned against using the views of a later Congress to construe a statute enacted many years before. See *Pension Benefit Guaranty Corporation* v. *LTV Corp.*, 496 U. S. 633, 650 (1990) (later history is "'a hazardous basis for inferring the intent of an earlier' Congress" (quoting *United States* v. *Price*, 361 U. S.

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304, 313 (1960))). And, while the majority suggests that the subsequent history "control[s] our construction" of the FDCA, see *ante*, at 20 (citation and internal quotation marks omitted), this Court expressly has held that such subsequent views are not "controlling." *Haynes* v. *United States*, 390 U. S. 85, 87–88, n. 4 (1968); accord, *Southwestern Cable Co.*, 392 U. S., at 170 (such views have "'very little, if any, significance'"); see also *Sullivan* v. *Finkelstein*, 496 U. S. 617, 632 (1990) (SCALIA, J., concurring) ("Arguments based on subsequent legislative history . . . should not be taken seriously, not even in a footnote.").

Regardless, the later statutes do not support the majority's conclusion. That is because, whatever individual Members of Congress after 1964 may have assumed about the FDA's jurisdiction, the laws they enacted did not embody any such "no jurisdiction" assumption. And one cannot automatically *infer* an antijurisdiction intent, as the majority does, for the later statutes are both (and similarly) consistent with quite a different congressional desire, namely, the intent to proceed without interfering with whatever authority the FDA otherwise may have possessed. See, *e.g.*, Cigarette Labeling and Advertising—1965: Hearings on H. R. 2248 et al. before the House Committee on Interstate and Foreign Commerce, 89th Cong., 1st Sess., 19 (1965) (hereinafter 1965 Hearings) (statement of Rep. Fino that the proposed legislation would *not* "erode" agency authority). As I demonstrate below, the subsequent legislative history is critically ambivalent, for it can be read *either* as (a) "ratif[ying]" a no-jurisdiction assumption, see *ante*, at 34, *or* as (b) leaving the jurisdictional question just where Congress found it. And the fact that both inferences are "equally tenable," *Pension Benefit Guaranty Corp.*, *supra*, at 650 (citation and internal quotation marks omitted); *Johnson* v. *Transportation Agency, Santa Clara Cty.*, 480 U. S. 616, 672 (1987) (SCALIA, J., dissenting), prevents the majority from drawing from the

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later statutes the firm, antijurisdiction implication that it needs.

Consider, for example, Congress' failure to provide the FDA with express authority to regulate tobacco—a circumstance that the majority finds significant. See *ante*, at 21, 24–25, 32–33. But cf. *Southwestern Cable Co., supra,* at 170 (failed requests do not prove agency "did not already possess" authority). In fact, Congress *both* failed to grant express authority to the FDA when the FDA denied it had jurisdiction over tobacco *and* failed to take that authority expressly away when the agency later asserted jurisdiction. See, *e.g.*, S. 1262, 104th Cong., 1st Sess., §906 (1995) (failed bill seeking to amend FDCA to say that "[n]othing in this Act or any other Act shall provide the [FDA] with any authority to regulate in any manner tobacco or tobacco products"); see also H. R. 516, 105th Cong., 1st Sess., §2 (1997) (similar); H. R. Res. 980, reprinted in 142 Cong. Rec. 5018 (1996) (Georgia legislators unsuccessfully requested that Congress "rescind any action giving the FDA authority" over tobacco); H. R. 2283, 104th Cong., 1st Sess. (1995) (failed bill "[t]o prohibit the [FDA] regulation of the sale or use of tobacco"); H. R. 2414, 104th Cong., 1st Sess., §2(a) (1995) (similar). Consequently, the defeat of various different proposed jurisdictional changes proves nothing. This history shows only that Congress could not muster the votes necessary either to grant or to deny the FDA the relevant authority. It neither favors nor disfavors the majority's position.

The majority also mentions the speed with which Congress acted to take jurisdiction away from other agencies once they tried to assert it. See *ante,* at 22, 26–29. But such a congressional response again proves nothing. On the one hand, the speedy reply might suggest that Congress somehow resented agency assertions of jurisdiction in an area it desired to reserve for itself—a consideration that supports the majority. On the other hand, Congress'

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quick reaction with respect to *other* agencies' regulatory efforts contrasts dramatically with its failure to enact any responsive law (at any speed) after the FDA asserted jurisdiction over tobacco more than three years ago. And that contrast supports the opposite conclusion.

In addition, at least one post-1938 statute reveals quite a different congressional intent than the majority infers. See Note following 21 U. S. C. §321 (1994 ed., Supp. III) (FDA Modernization Act of 1997) (law "shall [*not*] be construed to affect the question of whether the [FDA] has any authority to regulate any tobacco product," and "[s]uch authority, if any, shall be exercised under the [FDCA] as in effect on the day before the date of [this] enactment"). Consequently, it appears that the only interpretation that can reconcile *all* of the subsequent statutes is the inference that Congress did not intend, either explicitly or implicitly, for its later laws to answer the question of the scope of the FDA's jurisdictional authority. See 143 Cong. Rec. S8860 (Sept. 5, 1997) (the Modernization Act will "not interfere or substantially negatively affect any of the FDA tobacco authority").

The majority's historical perspective also appears to be shaped by language in the Federal Cigarette Labeling and Advertising Act (FCLAA), 79 Stat. 282, 15 U. S. C. §1331 *et seq.* See *ante*, at 25–26. The FCLAA requires manufacturers to place on cigarette packages, etc., health warnings such as the following:

> "SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy." 15 U. S. C. §1333(a).

The FCLAA has an express pre-emption provision which says that "[n]o statement relating to smoking and health, other than the statement required by [this Act], shall be required on any cigarette package." §1334(a). This pre-emption clause plainly prohibits the FDA from requiring

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on "any cigarette package" any other "statement relating to smoking and health," but no one contends that the FDA has failed to abide by this prohibition. See, *e.g.*, 61 Fed. Reg. 44399 (1996) (describing the other regulatory prescriptions). Rather, the question is whether the FCLAA's pre-emption provision does *more*. Does it forbid the FDA to regulate at all?

This Court has already answered that question expressly and in the negative. See *Cipollone* v. *Liggett Group, Inc.*, 505 U. S. 504 (1992). *Cipollone* held that the FCLAA's pre-emption provision does not bar state or federal regulation outside the provision's literal scope. *Id.*, at 518. And it described the pre-emption provision as "merely prohibit[ing] state and federal rulemaking bodies from mandating particular cautionary statements on cigarette labels . . . ." *Ibid.*

This negative answer is fully consistent with Congress' intentions in regard to the pre-emption language. When Congress enacted the FCLAA, it focused upon the regulatory efforts of the Federal Trade Commission (FTC), not the FDA. See 1965 Hearings 1–2. And the Public Health Cigarette Smoking Act of 1969, Pub. L. 91–222, §7(c), 84 Stat. 89, expressly amended the FCLAA to provide that "[n]othing in this Act shall be construed to affirm or deny the [FTC's] holding that it has the authority to issue trade regulation rules" for tobacco. See also H. R. Conf. Rep. No. 91–897, p. 7 (1970) (statement of House Managers) (we have "no intention to resolve the question as to whether" the FTC could regulate tobacco in a different way); see also 116 Cong. Rec. 7921 (1970) (statement of Rep. Satterfield) (same). Why would one read the FCLAA's pre-emption clause—a provision that Congress intended to limit even in respect to the agency directly at issue—so broadly that it would bar a different agency from engaging in any other cigarette regulation at all? The answer is that the Court need not, and should not, do so.

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And, inasmuch as the Court already has declined to view the FCLAA as pre-empting the entire field of tobacco regulation, I cannot accept that that same law bars the FDA's regulatory efforts here.

When the FCLAA's narrow pre-emption provision is set aside, the majority's conclusion that Congress clearly intended for its tobacco-related statutes to be the exclusive "response" to "the problem of tobacco and health," *ante*, at 35, is based on legislative silence. Notwithstanding the views voiced by various legislators, Congress itself has addressed expressly the issue of the FDA's tobacco-related authority only once—and, as I have said, its statement was that the statute was *not* to "be construed to affect the question of whether the [FDA] has any authority to regulate any tobacco product." Note following 21 U. S. C. §321 (1994 ed., Supp. III). The proper inference to be drawn from *all* of the post-1965 statutes, then, is one that interprets Congress' general legislative silence consistently with this statement.

IV

I now turn to the final historical fact that the majority views as a factor in its interpretation of the subsequent legislative history: the FDA's former denials of its tobacco-related authority.

Until the early 1990's, the FDA expressly maintained that the 1938 statute did not give it the power that it now seeks to assert. It then changed its mind. The majority agrees with me that the FDA's change of positions does not make a significant legal difference. See *ante*, at 34; see also *Chevron*, 467 U. S., at 863 ("An initial agency interpretation is not instantly carved in stone"); accord, *Smiley* v. *Citibank (South Dakota), N. A.*, 517 U. S. 735, 742 (1996) ("[C]hange is not invalidating"). Nevertheless, it labels those denials "important context" for drawing an inference about Congress' intent. *Ante*, at 34. In my view,

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the FDA's change of policy, like the subsequent statutes themselves, does nothing to advance the majority's position.

When it denied jurisdiction to regulate cigarettes, the FDA consistently stated *why* that was so. In 1963, for example, FDA administrators wrote that cigarettes did not satisfy the relevant FDCA definitions—in particular, the "intent" requirement—because cigarette makers did not sell their product with accompanying "therapeutic claims." Letter to Directors of Bureaus, Divisions and Directors of Districts from FDA Bureau of Enforcement (May 24, 1963), in Public Health Cigarette Amendments of 1971: Hearings on S. 1454 before the Consumer Subcommittee of the Senate Committee on Commerce, 92d Cong., 2d Sess., 240 (1972) (hereinafter FDA Enforcement Letter). And subsequent FDA Commissioners made roughly the same assertion. One pointed to the fact that the manufacturers only "recommended" cigarettes "for smoking pleasure." Two others reiterated the evidentiary need for "health claims." Yet another stressed the importance of proving "intent," adding that "[w]e have not had sufficient evidence of "intent with regard to nicotine." See, respectively, *id.*, at 239 (Comm'r Edwards); Letter of Dec. 5, 1977, App. 47 (Comm'r Kennedy); 1965 Hearings 193 (Comm'r Rankin); 1994 Hearings 28 (Comm'r Kessler). Tobacco company counsel also testified that the FDA lacked jurisdiction because jurisdiction "depends on . . . intended use," which in turn "depends, *in general*, on the claims and representations made by the manufacturer." Health Consequences of Smoking: Nicotine Addiction, Hearing before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce, 100th Cong., 2d Sess., 288 (1988) (testimony of Richard Cooper) (emphasis added).

Other agency statements occasionally referred to additional problems. Commissioner Kessler, for example, said

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that the "enormous social consequences" flowing from a decision to regulate tobacco counseled in favor of obtaining specific Congressional "guidance." 1994 Hearings 69; see also *ante,* at 31 (quoting statement of Health and Human Services Secretary Brandt to the effect that Congress wanted to make the relevant jurisdictional decision). But a fair reading of the FDA's denials suggests that the overwhelming problem was one of proving the requisite manufacturer intent. See *Action on Smoking and Health* v. *Harris,* 655 F. 2d 236, 238–239 (CADC 1980) (FDA "comments" reveal its "understanding" that "the crux of FDA jurisdiction over drugs lay in manufacturers' representations as revelatory of their intent").

What changed? For one thing, the FDA obtained evidence sufficient to prove the necessary "intent" despite the absence of specific "claims." See *supra,* at 12–14. This evidence, which first became available in the early 1990's, permitted the agency to demonstrate that the tobacco companies *knew* nicotine achieved appetite-suppressing, mood-stabilizing, and habituating effects through chemical (not psychological) means, even at a time when the companies were publicly denying such knowledge.

Moreover, scientific evidence of adverse health effects mounted, until, in the late 1980's, a consensus on the seriousness of the matter became firm. That is not to say that concern about smoking's adverse health effects is a new phenomenon. See, *e.g.,* Higginson, A New Counterblast in Out-door Papers 179, 194 (1863) (characterizing tobacco as "'a narcotic poison of the most active class'"). It is to say, however, that convincing epidemiological evidence began to appear mid-20th century; that the First Surgeon General's Report documenting the adverse health effects appeared in 1964; and that the Surgeon General's Report establishing nicotine's addictive effects appeared in 1988. At each stage, the health conclusions were the subject of controversy, diminishing somewhat over time,

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until recently—and only recently—has it become clear that there is a wide consensus about the health problem. See 61 Fed. Reg. 44701–44706 (1996).

Finally, administration policy changed. Earlier administrations may have hesitated to assert jurisdiction for the reasons prior Commissioners expressed. See *supra*, at 27–28. Commissioners of the current administration simply took a different regulatory attitude.

Nothing in the law prevents the FDA from changing its policy for such reasons. By the mid-1990's, the evidence needed to prove objective intent—even without an express claim—had been found. The emerging scientific consensus about tobacco's adverse, chemically induced, health effects may have convinced the agency that it should spend its resources on this important regulatory effort. As for the change of administrations, I agree with then-JUSTICE REHNQUIST's statement in a different case, where he wrote:

> "The agency's changed view . . . seems to be related to the election of a new President of a different political party. It is readily apparent that the responsible members of one administration may consider public resistance and uncertainties to be more important than do their counterparts in a previous administration. A change in administration brought about by the people casting their votes is a perfectly reasonable basis for an executive agency's reappraisal of the costs and benefits of its programs and regulations. As long as the agency remains within the bounds established by Congress, it is entitled to assess administrative records and evaluate priorities in light of the philosophy of the administration." *Motor Vehicle Mfrs. Assn. of United States, Inc.* v. *State Farm Mut. Automobile Ins. Co.*, 463 U. S. 29, 59 (1983) (concurring in part and dissenting in part).

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V

One might nonetheless claim that, even if my interpretation of the FDCA and later statutes gets the words right, it lacks a sense of their "music." See *Helvering* v. *Gregory*, 69 F. 2d 809, 810–811 (CA2 1934) (L. Hand, J.) ("[T]he meaning of a [statute] may be more than that of the separate words, as a melody is more than the notes . . ."). Such a claim might rest on either of two grounds.

First, one might claim that, despite the FDA's legal right to change its mind, its original statements played a critical part in the enactment of the later statutes and now should play a critical part in their interpretation. But the FDA's traditional view was largely premised on a perceived inability to prove the necessary statutory "intent" requirement. See, *e.g.*, FDA Enforcement Letter 240 ("The statutory basis for the exclusion of tobacco products from FDA's jurisdiction is the fact that tobacco marketed for chewing or smoking without accompanying therapeutic claims, does not meet the definitions . . . for food, drug, device or cosmetic"). The statement, "we cannot assert jurisdiction over substance X unless it is treated as a food" would not bar jurisdiction if the agency later establishes that substance X is, and is intended to be, eaten. The FDA's denials of tobacco-related authority sufficiently resemble this kind of statement that they should not make the critical interpretive difference.

Second, one might claim that courts, when interpreting statutes, should assume in close cases that a decision with "enormous social consequences," 1994 Hearings 69, should be made by democratically elected Members of Congress rather than by unelected agency administrators. Cf. *Kent* v. *Dulles*, 357 U. S. 116, 129 (1958) (assuming Congress did not want to delegate the power to make rules interfering with exercise of basic human liberties). If there is such a background canon of interpretation, how-

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Produced by R.J. Reynolds Tobacco Company in response to FTC Subpoena

FEBRUARY

BROWN & WILLIAMSON TOBACCO CORPORATION

1600 West Hill Street Louisville, Kentucky 40201

March 14, 1978

CONFIDENTIAL

MESSRS. AHRENSFELD
STEVENS
GREER
CROHN
BENSON

PLAINTIFF'S EXHIBIT 6 Dr. Spears

Gentlemen:

RE: FTC Smoking Machine for Carbon Monoxide Analysis

There is reason to believe that the FTC has received from Phipps and Bird a new smoking machine for carbon monoxide analysis, and that it has been in use at the FTC since December 1977.

The Commission may announce that it is testing cigarette smoke for carbon monoxide together with "tar" and nicotine, and ask the companies to publish the results as they apply to particular brands. Because of this possibility, it has been suggested that the industry should do some initial background work in gathering data in order to be prepared to respond to any initiative by the FTC.

No action should be taken which would in any way expedite the Commission's consideration of CO.

In the interest of careful consideration of the facts and full development of the best arguments and positions relative to CO testing, the suggestion has been made that each company should conduct carbon monoxide tests utilizing monitor cigarettes. In addition to a normal "tar" delivery cigarette, a low "tar" monitor might be employed as well. Each company would forward its data in blind form, i.e. method undisclosed and company undisclosed, to Covington & Burling who would then forward the data to Dr. Arkin for statistical analysis. Such an analysis could produce useful information as to inherent deficiencies in any carbon monoxide testing program for either regular "tar" or low "tar" products as proposed by the Commission as well as in the required sample size.

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The analysis might be useful in the presentation of the industry's objections to a proposed FTC program to undertake carbon monoxide testing in a machine that reads CO along with "Tar" and nicotine. In addition Dr. Arkin might be available as a witness on this subject.

To restate, each company would determine CO delivery using the reference cigarettes and its respective testing methods. Only the analytical data would be sent to Dr. Topol who in turn would ask Dr. Arkin to do a preliminary evaluation of the inter-laboratory variations. There would be no discussion or passage of information at this time on the various methods used.

This matter will be discussed tomorrow evening, March 15.

Cordially,

Ernie Pepples

EP/dlt

cc: Mr. William Shinn

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Mr A Yeaman

8

PHILIP MORRIS

U.S.A.

RESEARCH CENTER: P.O. BOX 30, RICHMOND, VIRGINIA 23206 TELEPHONE (703) 275-8361

PLAINTIFF'S EXHIBIT 7 Dr. Spears

October 24, 1969

Read 10/24/69

Allan Topol, Esq.
Covington & Burling
888 Sixteenth Street N.W.
Washington, D.C. 20006

Dear Allan:

I am pleased to advise you that the technical representatives of the sponsors of the Chemosol test program have all approved the protocols described as follows:

1. The Hazleton Protocol-Research Proposal No. P-454-102 for carrying out the bioassay test, and

2. The protocol for manufacture of Chemosol treated and control cigarets, dated October 1, 1969. These protocols are contained in the attached copy of the Protocol Subcommittee Report in the form of a letter dated October 2, 1969, with attachments, from Dr. Eldon Nielson, Chairman of the Subcommittee.

It has been agreed for the manufacture of the cigarets that the P. Lorillard Company would prepare the strips of tobacco, blended in the proper proportions to match the Kentucky Reference Cigaret formula, and ship them to R. J. Reynolds Company in Winston-Salem for treatment and conversion into the finished cigarets. Accordingly, Dr. Murray Senkus, of Reynolds, will name the person who will act as the industry technical representative in your negotiations with American Chemosol Corporation for the purpose of specifying the conditions of treatment and securing the certification of the sample, as mentioned in my letter addressed to Mr. Thomas Austern, dated September 26, 1969.

Please be reminded of our recommendation that the industry side insist that the American Chemosol Corporation not give any publicity to the submission of these two protocols to them for their examination or to reveal in any way the details of the test program to the public press. We believe that this testing should be done quietly and without fanfare.

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If you or your associates require any further amplification of the protocols or wish to discuss the program as a whole from a technical point of view, I suggest that we call a meeting of the technical representatives at some mutually convenient date for this purpose.

Sincerely yours,

H. Wakeham

H. Wakeham, Vice President
Corporate Research and Development

cc: Mr. Word B. Bennett
Mr. James Wood
Dr. Murray Senkus
Dr. A. W. Spears
Dr. W. W. Bates
Dr. R. A. Sanford
Mr. W. Brooks George
Mr. Edward S. Harlow

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Lorillard
TOBACCO COMPANY

MEMORANDUM

Internal Memo # 4376

March 1, 1996

TO: M. A. Sudholt

FROM: R. T. Walker

SUBJECT: The Effect of Diammonium Phosphate (DAP) on Smoke pH and Nicotine Delivery

PROJECT NO.: Q 449 Analytical Support

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FINDINGS:

An increase in application of diammonium phosphate to the tobacco blend had little effect on total and puff by puff smoke pH and had no significant effect on puff by puff nicotine, TPM, and ratio of nicotine to TPM delivery. The total nicotine to CPM ratio was not affected by increased DAP.

INTRODUCTION:

It has been reported by Armitage and Turner that the rate of absorption of nicotine by the smoker is dependent on the pH of the delivered smoke. Nicotine in basic tobacco smoke, like that of cigars, is unprotonated and more readily absorbed than nicotine in more acidic tobacco smoke, like that of cigarettes (1).

Diammonium phosphate (DAP), $(NH_4)_2HPO_4$, is used at low levels in the manufacturing of Lorillard brand cigarettes. Because DAP has a basic pH of 8 (2), there has been some concern about what effect its use in cigarette blends may have on the pH of the cigarette smoke and the delivery of nicotine. The objective of this study was to determine if an application level higher than that currently being used would affect the pH and level of delivery of nicotine in cigarette smoke.

In a previous study (3), several cigarette samples were made with DAP concentration in the range of 0.4% (control) to 3.0% by weight. Standard Smoking Lab and Leaf Lab analyses were performed. Nicotine yields per puff were calculated by dividing the total yield by the number of puffs. Smoke pH was measured for the total cigarette. An increased level of DAP was found to retard the burn rate of the cigarette, thereby increasing puff count.

PLAINTIFF'S EXHIBIT 8 Dr. Spears

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In this study, two cigarette samples with different levels of DAP were compared. Particulates for each puff were collected. Puff by puff pH and yields of nicotine and TPM were determined in order to better simulate the delivery to the smoker. Total cigarette smoke pH and water soluble phosphate on the tobacco were also determined. Standard Smoking Lab and Leaf Lab analyses were performed.

EXPERIMENTAL:

Sample Preparation

Two trays of each sample were prepared by K. Barrett of Product Development. The control, coded as Sample 1411, was prepared with 0% application of DAP. The sample, coded as Sample 1412, was prepared with a 2.6% DAP application by addition of 589.68 grams of DAP to the burley casing. Because RL is manufactured with DAP, the control and the sample had a final calculated concentration of 0.4% and 3.0%, respectively. The samples were conditioned at 72°F ± 2°F and 60% ± 2% relative humidity for two weeks before testing was continued.

Smoking Lab Analysis

Sufficient quantities of each sample were selected based on weight and pressure drop for testing. Cigarettes were analyzed by standard methods. Five replicates were made of each sample with 5 cigarettes per pad. Pressure drop is the average of 25 cigarettes.

Leaf Lab Analysis

Batches of each tobacco sample were submitted to H. Efird and M. Snopkowski of the Leaf Lab for analysis. Duplicates of each sample were analyzed.

IC Analysis for Phosphate

Cigarettes from each sample were submitted to F. Perini for analysis by ion chromatography (IC) for determination of water soluble phosphate concentration (4). Four replicates of each sample were analyzed and the results were reported as percent hydrogen phosphate.

Smoking Procedures

Standard smoking methods (5) were used. For puff by puff analysis, each sample was divided into sets of 45 cigarettes. Each set was smoked in 5 rounds of 9 cigarettes with 1 clearing puff per round. Particulates were collected onto Cambridge filter pads for each puff. Cigarettes were smoked to a butt length of 36mm. Total particulate matter (TPM) was calculated by weighing

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each filter pad before and after use. This method was followed for puff by puff smoke pH and puff by puff nicotine analyses.

For analysis of total cigarette smoke pH, 5 cigarettes were smoked per pad. Total particulate matter (TPM) was calculated.

A Borgwaldt RM CS/20 smoking machine with a twin filter attachment was used for smoking the cigarettes. The smoking machine was calibrated to draw a 35ml puff from each cigarette once per minute. It was set to mode 10 and partial puff counts were recorded.

Smoke pH Analysis

Following an established method (6), each pad was transferred to a 100ml beaker and extracted with CO_2-free deionized water[1] with 5 minutes of stirring under a nitrogen atmosphere. For each extract, pH readings were taken after allowing contact between the solution and the electrode for 5 minutes under an atmosphere of nitrogen. Six replicate sets of the 0.4% DAP control and eight replicate sets of the 3.0% DAP sample were analyzed. An unused filter pad was treated as the sample solutions and determined to have a pH of 9.77.

A Fisher Accumet Model 805 MP pH meter equipped with a combination silver-silver chloride electrode was used for the pH measurements. The meter was calibrated with pH 4 and pH 10 buffer solutions to an efficiency of at least 0.95.

Nicotine Analysis

Four replicate sets of 45 cigarettes were analyzed for both the 0.4% DAP control and the 3.0% DAP sample. Sample pads were extracted using isopropanol with 35 minutes of agitation on a mechanical shaker. Anethole was used as an internal standard. Sample extracts were filtered into autosampler vials using 0.45µm pore membrane filters. Nicotine concentration in the extracts was determined by G. Dumas of the Smoking Lab by standard GC methods.

RESULTS:

The data were compared statistically using "t" and "F" tests. Nicotine: TPM and pH puff by puff profile shapes were compared statistically using correlation-based algorithms (7). Results from the previous study (3) and the current study were compared. Data from the two studies were not compared as there is the possibility of differences between the samples from the two

[1]The pH of the water should be in the range of 6.5 to 7.2.

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studies due to other variables such as differences in the tobacco blends, or differences in uptake of DAP.

Tobacco and Total Smoke Comparisons

1. With respect to Smoking Lab data, the 0.4% DAP control and the 3.0% DAP sample were statistically similar. The 3.0% sample had a higher puff count than the control sample. The means and standard deviations for five replicate trials are reported in Table 1. From the previous study, the 3.0% sample had statistically higher values than the control for nicotine, CPM, and ratio of nicotine to CPM(3). The 3.0% sample also had a higher puff count than the control.

Table 1. Smoking Lab Data

	Control (0.4%)		Sample (3.0%)	
	Mean	Std dev	Mean	Std dev
Nic (mg/puff)	0.148	0.003	0.153	0.010
CPM (mg/puff)	2.20	0.06	2.22	0.13
Nic:CPM	0.0675	0.0011	0.0692	0.0012
Nic (mg/cig)	1.26	0.03	1.38	0.09
CPM (mg/cig)	18.66	0.57	19.95	1.15
Puff count	8.5	0.2	9.0	0.2

2. Leaf Lab data for the two samples appeared similar[2] except for % nitrogen, % TVB, and pH for which the values for the 3.0% sample appear to be greater. See Table 2 for data. Similar results were found in the previous study.

[2]Statistical comparisons are not possible for Leaf Lab data.

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Table 2. Leaf Lab Data

	Control (0.4%)	Sample (3.0%)
% Nitrogen	2.83	3.06
% TVB	0.52	0.78
% Nicotine	1.89	1.85
% Ash	14.5	14.5
% TRS	8.0	7.6
Vol	212.0	219.0
pH	5.30	5.44

3. The level of water soluble phosphate, reported as HPO_4^{2-}, was determined to be statistically greater for the 3.0% sample, at 1.53% ± 0.06%, than for the 0.4% control, at 0.69% ± 0.09%. The results confirmed that the 3.0% sample, contained significantly greater amounts of phosphate than the control sample.

4. The total cigarette smoke pH was greater for the 3.0% sample, at 6.33 ± 0.03, than for the control, at 6.15 ± 0.03. The TPM was determined to be 2.53 ± 0.02 for the control and 2.37 ± 0.13 for the 3.0% sample. Results from the previous study indicated no difference between the control and the 3.0% sample with respect to total smoke pH.

Puff by Puff Comparisons

1. The puff counts for the 3.0% sample were higher than for 0.4% control. For the puff by puff pH analysis, the 3.0% sample smoked to 8.9 puffs on average. The control smoked to 7.9 puffs. For the nicotine analysis, the 3.0% sample had an average puff count of 8.8 and the control had an average puff count of 8.1.

2. With respect to puff by puff smoke pH, the 0.4% control had a statistically higher pH than the 3.0% sample for puffs one, two, three, five, and six. See Figure 1 for comparison plots. The means and standard deviations for six and eight replicate sets for the control and the 3.0% sample, respectively, are shown in Table 3.

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Table 3. Puff by Puff Smoke pH

	Control (0.4%)		Sample (3.0%)	
Puff	Mean	Std dev	Mean	Std dev
1	7.06	0.12	6.44	0.46
2	7.10	0.08	6.57	0.41
3	7.21	0.35	6.58	0.32
4	6.97	0.09	6.54	0.36
5	6.91	0.09	6.48	0.33
6	6.78	0.06	6.37	0.30
7	6.67	0.31	6.31	0.29
8	6.62	0.32	6.35	0.31
9			6.48	0.46

3. For all puffs, total particulate matter was not statistically different for the control and the 3.0% sample. See Figure 2 for TPM puff by puff plots. See Table 4 for the means and standard deviation for four replicate sets from the puff by puff nicotine study.

Table 4. Puff by Puff TPM (mg/puff)*

	Control (0.4%)		Sample (3.0%)	
Puff	Mean	Std dev	Mean	Std dev
1	1.55	0.12	1.34	0.19
2	1.62	0.17	1.59	0.31
3	2.00	0.04	1.90	0.19
4	2.11	0.05	2.02	0.21
5	2.30	0.05	2.33	0.05
6	2.36	0.25	2.50	0.06
7	2.50	0.26	2.69	0.03
8	3.02**	0.72	2.74	0.55
9	2.47**	1.44	3.79**	0.61
total	19.93		20.90	

*From the puff by puff nicotine analysis
**partial puff; partial puffs often yield poor precision

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4. The per puff delivery of nicotine was similar for all puffs for the control and the 3.0% sample. See Figure 3 for puff by puff comparison plots. The means and standard deviations for four replicate sets are shown in Table 5 for each sample.

Table 5. Puff by Puff Nicotine (µg/puff)

	Control (0.4%)		Sample (3.0%)	
Puff	Mean	Std dev	Mean	Std dev
1	83.94	3.67	75.84	10.86
2	108.0	12.0	108.2	24.5
3	135.9	4.5	131.7	13.1
4	142.6	3.5	139.6	19.7
5	156.0	6.6	161.5	5.5
6	154.6	16.0	179.4	26.5
7	160.3	18.6	177.5	0.6
8	164.4*	32.0	175.6	37.3
9	133.6*	68.6	199.6*	25.2
total	1339.4		1349.0	

*partial puff

5. The ratio of nicotine to TPM was statistically similar for all puffs except puff eight for which the value for the 3.0% sample was higher. See Table 6 and Figure 4 for comparisons.

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Table 6. Ratio of Nicotine to TPM Data

	Control (0.4%)		Sample (3.0%)	
Puff	Mean	Std dev	Mean	Std dev
1	0.0543	0.0027	0.0565	0.0018
2	0.0666	0.0012	0.0678	0.0027
3	0.0675	0.0013	0.0693	0.0010
4	0.0676	0.0015	0.0686	0.0021
5	0.0678	0.0015	0.0693	0.0014
6	0.0654	0.0011	0.0717	0.0091
7	0.0641	0.0014	0.0664	0.0009
8	0.0549*	0.0039	0.0640	0.0018
9	0.0553*	0.0053	0.0530*	0.0019

*partial puff

6. The puff by puff nicotine:TPM plots were determined to have statistically similar shapes. The puff by puff smoke pH plots were determined to have statistically different shapes.

DISCUSSION:

The addition of excess DAP appears to have had a relatively small effect on the pH of the tobacco smoke. For the five puffs which were statistically different, the average puff by puff smoke pH of the control was 6.2% to 9.2% higher than the sample. The pH of the sample was 2.9% higher than the control for average total cigarette smoke pH. This is reasonable because the smoke resulting from the burning of cigarettes is a very complex matrix. Tobacco smoke is highly buffered against changes in pH (8).

The puff by puff pH values for the 3.0% sample were slightly lower than those for the 0.4% control for values which were statistically different. Conversely, the total cigarette smoke pH was slightly higher for the 3.0% sample than for the control. Although these results were unexpected, they were very reproducible. The percent relative standard deviations (%RSD) for puff by puff pH ranged from 0.9% to 4.8% for six replicate sets of the control sample and ranged from 4.6% to 7.1% for eight replicate sets of the 3.0% sample. For total smoke pH analysis,

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the %RSDs were 0.4% for each of the samples. A stronger emphasis should be placed on the puff by puff data because this method more closely simulates the act of cigarette smoking.

CONCLUSIONS:

In the puff by puff pH analysis, the control sample, with 0.4%(w/w) applied DAP, had a slightly higher pH for five of the eight puffs compared. For total smoke pH, the sample, with a 3.0%(w/w) application of DAP, had a higher pH at 6.33 ± 0.03 than the control at 6.15 ± 0.03, but its pH was still acidic. The shapes of the puff by puff pH profiles were statistically different for the two samples.

No differences were detected in the TPM and nicotine puff by puff data. The ratio of nicotine to TPM was statistically similar for all but one puff. The puff counts for the 3.0% sample were greater than for the control. The shapes of the puff by puff nicotine:TPM profiles were similar for the control and the sample.

FUTURE STUDIES:

The smoke pH method used in this analysis has proven to be adequate for comparative studies but is only an approximate measure for the pH of tobacco smoke (9). It is recommended that an attempt be made at developing a method that would be suitable for more experimental circumstances. Also recommended is exploration of the relative dependence of puff by puff pH on TPM. It has been reported in the literature that for total cigarette analyses, pH is strongly dependent on total particulate matter (10).

R. T. Walker

vlm:v908

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Figure 1. Puff by Puff pH Comparison

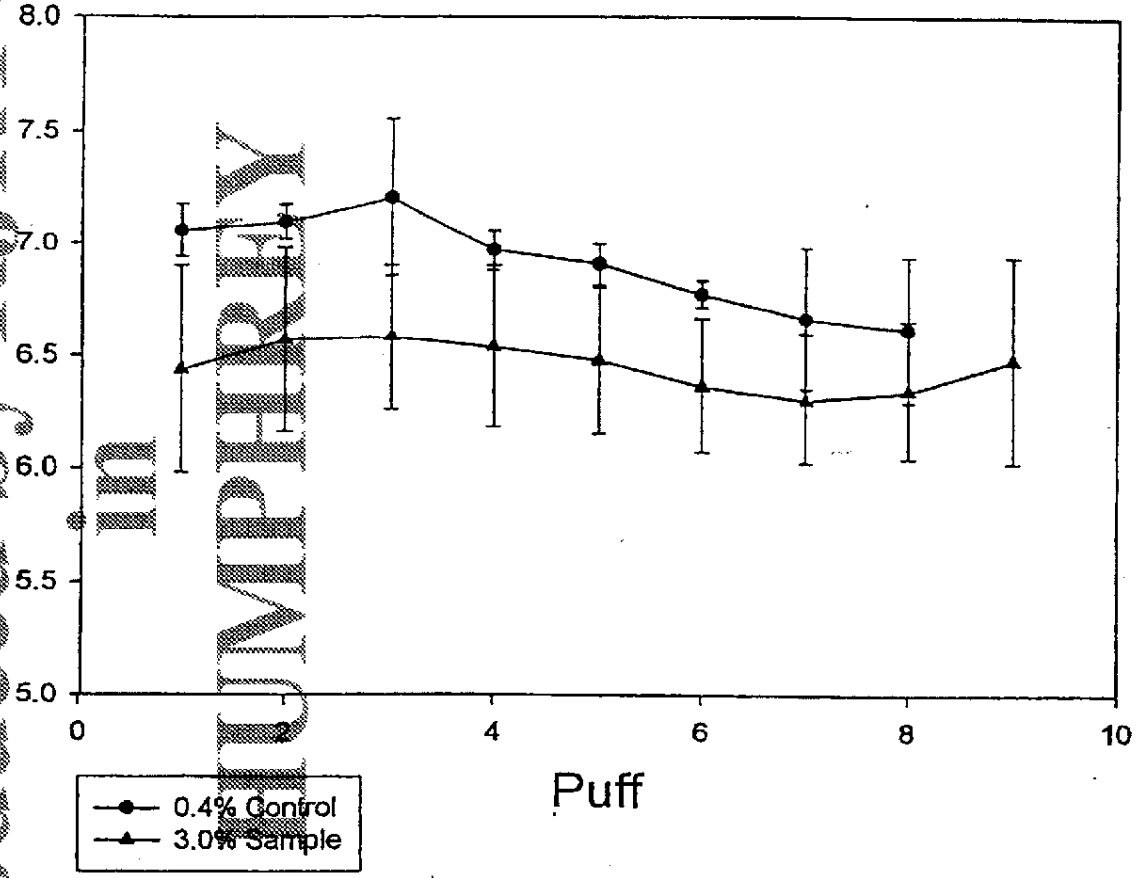

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Figure 2. Puff by Puff TPM Comparison

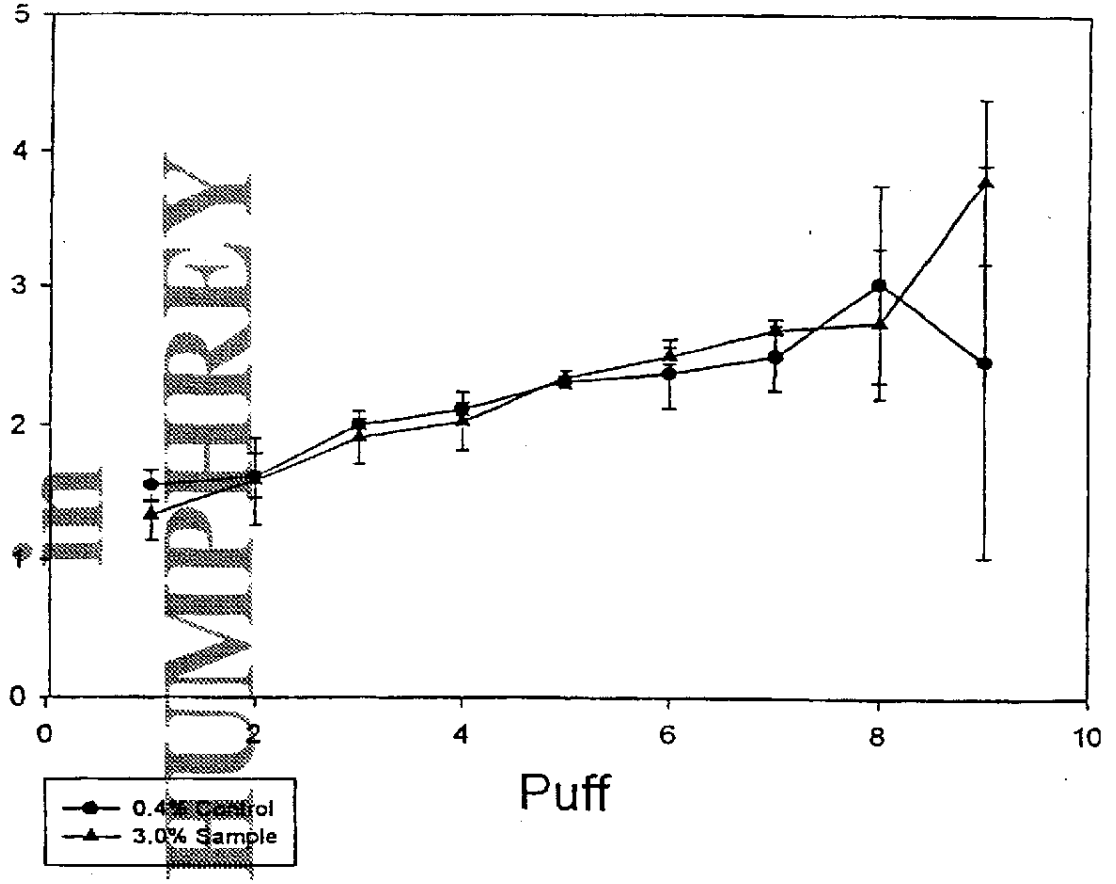

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Figure 3. Puff by Puff Nicotine Comparison

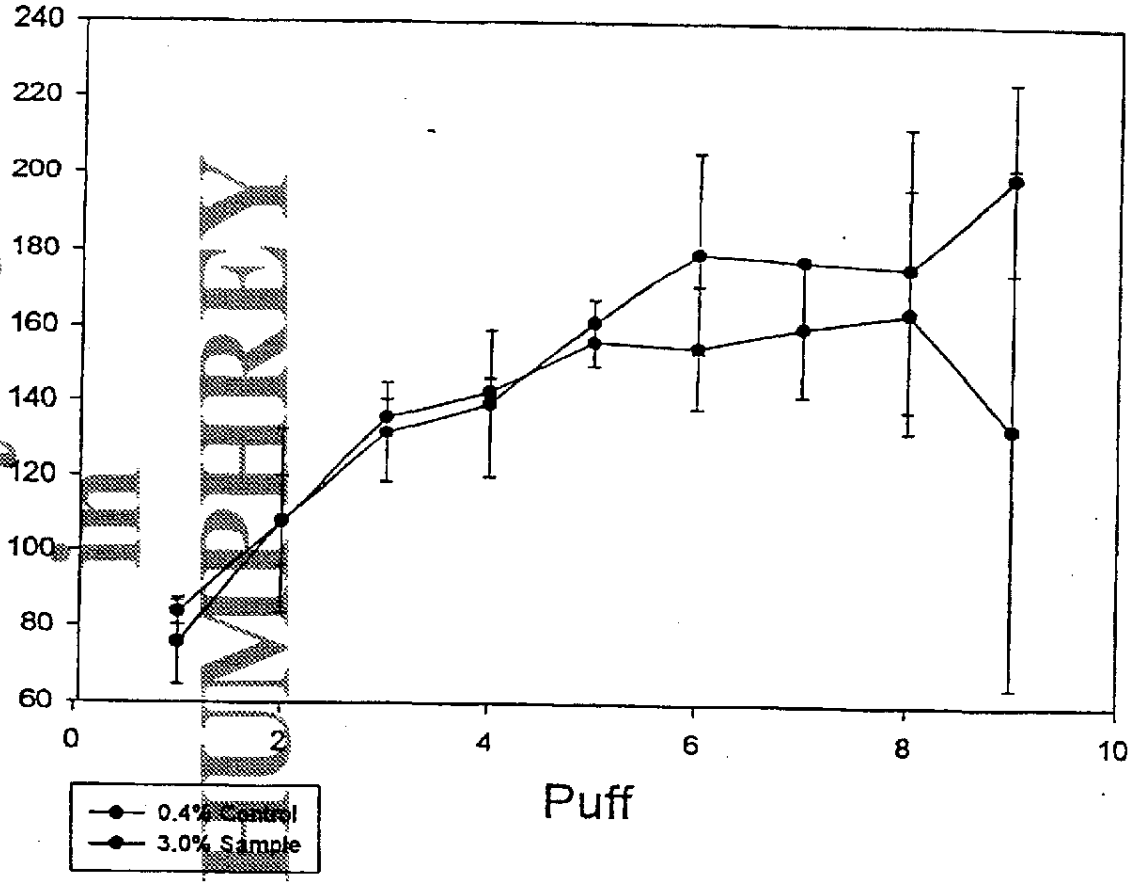

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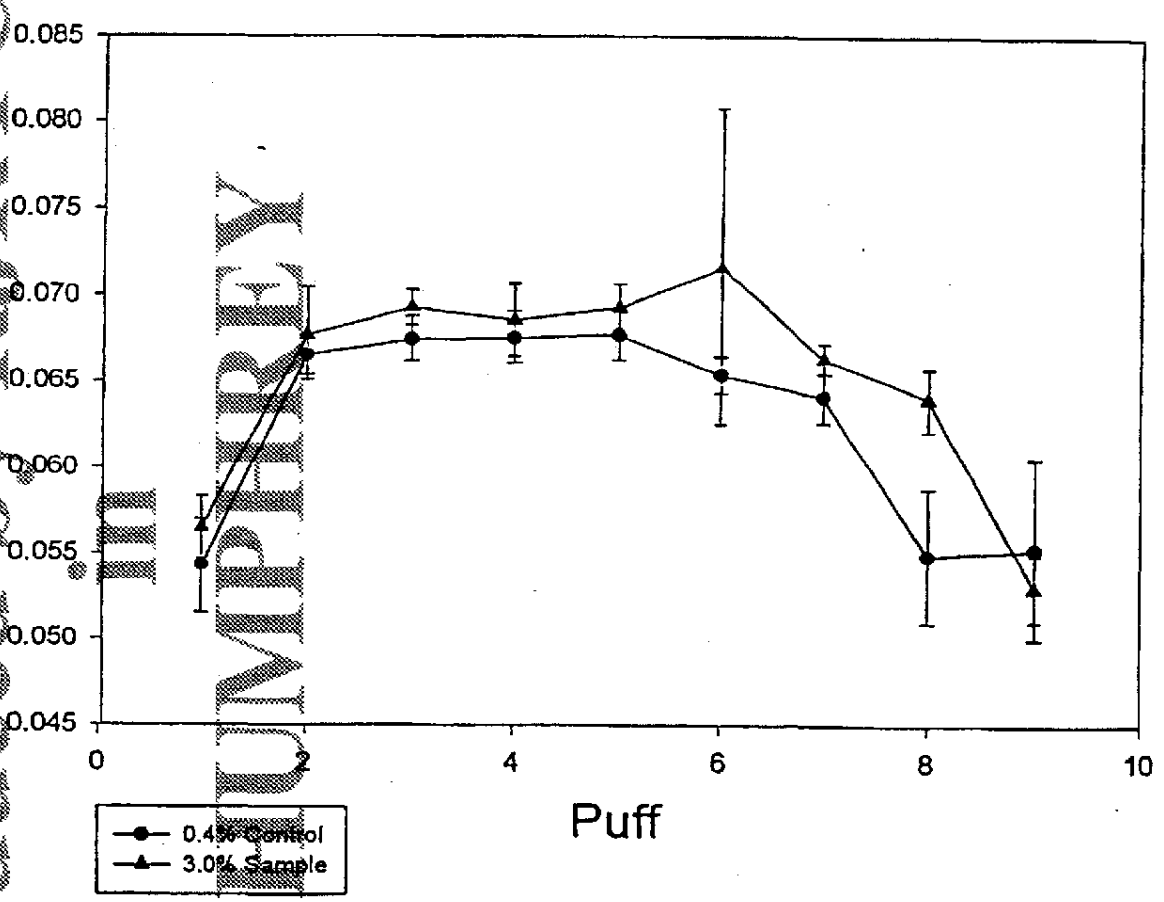
Figure 4. Nicotine:TPM Comparison



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Lorillard
TOBACCO COMPANY

MEMORANDUM

Internal Memo # 4613

PLAINTIFF'S EXHIBIT 9 Dr. Spears

September 18, 1996

TO: M. A. Sudholt

FROM: J. M. Johnson

SUBJECT: Summary of the Effects of Ammonium Carbonate, Ammonium Bicarbonate, Urea and Diammonium Phosphate on Smoke pH, Smoke Data and Leaf Chemistry

PROJECT NO.: [redacted] Analytical Support

FINDINGS:

Tobacco nicotine was not affected by the additives. The four additives studied, urea, ammonium carbonate, ammonium bicarbonate and diammonium phosphate, were found to modify the smoke delivery of nicotine and corrected particulate matter. Urea, ammonium carbonate and ammonium bicarbonate additives were found to increase the comparative pH of the collected smoke particulates.

INTRODUCTION:

The smoke pH, mainstream smoke delivery and leaf chemistry data for cigarettes with different concentration levels of the additives urea, ammonium carbonate (AC), ammonium bicarbonate (ABC), and diammonium phosphate (DAP) were determined (1,2). Statistical evaluations of the data to determine significant differences between the control and additive cigarettes were performed (3). Group and pairwise analyses were performed on mainstream smoke delivery data to determine if mean differences among the cigarettes at all concentrations for a single additive were greater than would be expected by chance and, if so, which concentration level cigarettes were different from the control. Trend analyses were also performed to determine if the results increased, decreased or did not correlate as the percent additive was increased. Trend analyses were performed on smoke pH, mainstream smoke delivery, leaf chemistry and nicotine transfer data.

This memorandum provides a summary of the results obtained from the statistical evaluations. An additive was determined to have an impact if a trend or threshold effect was evident. In some cases, lower additive level cigarettes were significantly different from the control while higher additive level cigarettes were not significantly different from the control. This indicated that the additive was not the cause for the differences which were found.

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In evaluating smoke pH data, it should be noted that the reported smoke pH is a measurement of the pH of an aqueous extraction of collected smoke particulates. The Henderson-Haselbach equation (4) relates the pH of aqueous extractions of collected smoke particulates to percent levels of protonated and unprotonated nicotine in the aqueous solutions. Increases in smoke pH can result in increases in the calculated percent unprotonated nicotine in an aqueous solution. It is not known whether a similar effect would occur in the smoke aerosol.

EXPERIMENTAL:

The control and additive cigarettes were made by the Product Development Department. Cigarettes containing urea, ammonium carbonate (AC) or ammonium bicarbonate (ABC) were made with an Old Gold 85 construction. The additives were applied to the tobacco at 0% (the control), 0.5%, 1.0%, 1.5% and 2.0% levels. The cigarettes containing diammonium phosphate (DAP) were made with a Newport 85 construction and the additive was applied at 0.4% (the control), 1.0%, 2.0% and 3.0% levels.

Leaf Laboratory and Smoking Laboratory personnel performed the leaf chemistry and mainstream smoke delivery analyses. Comparative smoke pH analyses were performed by members of the Research Analytical Development Section. The percent unprotonated nicotine in aqueous solutions and the percent nicotine transfer from leaf to smoke was calculated from the experimental data.

The group statistical analysis method used was One Way Analysis of Variance (ANOVA) and the pairwise statistical analysis method used was either Dunn's or Dunnett's Pairwise Multiple Comparison. The statistical analyses were run at a 95% confidence level. Dunn's and Dunnett's tests are advanced forms of the student t-test. Dunnett's test was used when the sample sizes were equal and Dunn's test was used when the sample sizes were not equal. These statistical analyses were performed on mainstream smoke delivery data only. The results of these statistical tests are displayed in Table 1. In the cases where a statistical difference was found using the pairwise test, the average percent difference relative to the control is given.

The Pearson Product Moments Correlation run at a 95% confidence level was used to establish trends. Trend analyses were performed on smoke pH, mainstream smoke delivery and leaf chemistry and nicotine transfer data. Data used in these analyses are shown in Tables 2 through 5.

The following Smoking Lab data were evaluated: 1) mg nicotine per cigarette, 2) mg corrected particulate matter (CPM) per cigarette, 3) puff count per cigarette, 4) mg nicotine per puff, 5) mg CPM per puff, 6) nicotine per CPM and 7) nicotine per CPM per puff. The following leaf chemistry data were evaluated: 1) percent nitrogen, 2) percent total volatile bases (TVB), 3) percent nicotine, 4) percent total reducing substances (TRS) and 5) tobacco pH.

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RESULTS:

UREA

The addition of urea to cigarette tobacco was found to increase the 1) nicotine per CPM, 2) percent nicotine transfer from leaf to smoke per cigarette and 3) smoke pH. A summary of the effects of adding urea to cigarette tobacco, based on results from statistical evaluations of the analytical data, is shown below.

Tobacco Chemistry

The addition of urea to the tobacco did not affect the percent nicotine in the tobacco blend or the leaf pH. As the percent added urea was increased, corresponding increases were seen in the percent nitrogen, percent TVB and percent TRS in the tobacco.

Mainstream Smoke Delivery

The addition of urea to cigarettes without filters did not affect the following mainstream smoke variables: 1) nicotine per cigarette, 2) CPM per cigarette, 3) puffs per cigarette, 4) nicotine per puff, 5) CPM per puff and 6) nicotine per CPM per puff. Results for the filtered cigarette were similar.

The addition of urea to unfiltered cigarettes did affect the nicotine per CPM ratio in the mainstream smoke.

Nicotine per CPM

A positive trend was observed between the increasing delivery of nicotine per CPM and an increasing level of urea in unfiltered cigarettes. Nicotine per CPM increased from 0.077 (control) to 0.085 (2.0% urea) which represented percent increases ranging from 5 to 11%. The corresponding filtered cigarettes did not show this increase in nicotine per CPM with urea concentration. Variations in filtration may have obscured the relatively small effect of urea on the nicotine per CPM ratio.

Percent Nicotine Transfer

A positive trend was observed between increasing levels of urea and increases in the percent transfer of nicotine from the leaf to the smoke on a per cigarette basis. This effect was observed in both the unfiltered and filtered cigarettes. The percent nicotine transfer increased from 12.1% (control) to 13.5% (2.0% urea) in the unfiltered cigarettes and from 6.5% (control) to 7.0% (2.0% urea) in the filtered cigarettes.

Comparative Smoke pH - Filtered Cigarettes

As the percent of added urea was increased, the comparative smoke pH increased from 6.70 (control) to 7.19 (2.0% urea). The observed smoke pH increase for urea cigarettes would increase the calculated percent unprotonated nicotine in an aqueous solution from about 5% (control) to 13% (2.0% urea).

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AMMONIUM CARBONATE

The addition of ammonium carbonate (AC) to cigarette tobacco was found to increase the 1) leaf pH, 2) nicotine per puff, 3) nicotine per CPM, 4) nicotine per CPM per puff, 5) percent nicotine transfer from leaf to smoke per puff and 6) smoke pH. A summary of the effects of adding ammonium carbonate to cigarette tobacco, based on results from statistical evaluations of the analytical data, is shown below.

Tobacco Chemistry

The addition of ammonium carbonate to the tobacco did not affect the percent nicotine or the percent TRS in the tobacco blend. As the percent added ammonium carbonate was increased, corresponding increases were seen in the percent nitrogen, percent TVB and leaf pH of the tobacco.

Mainstream Smoke Delivery

The addition of ammonium carbonate to unfiltered cigarettes did not affect the following mainstream smoke variables: 1) nicotine per cigarette, 2) CPM per cigarette, 3) puffs per cigarette and 4) CPM per puff. Results from the filtered cigarettes were similar.

The addition of ammonium carbonate in unfiltered cigarettes did affect the following smoke variables: 1) nicotine per puff, 2) nicotine per CPM and 3) nicotine per CPM per puff.

Nicotine per CPM

The addition of ammonium carbonate to unfiltered cigarettes increased the nicotine per CPM ratio from 0.077 (control) to 0.088. The percent increases ranged from 4 to 14% relative to the control. The nicotine per CPM was not found to increase with increasing levels of additive, as in a trend. Rather there appeared to be a threshold concentration, less than or equal to 0.5% ammonium carbonate, above which the impact of the additive was not related to concentration. This has been noted as a threshold effect (3). The corresponding filtered cigarettes showed similar effects.

Nicotine per Puff and Nicotine per CPM per Puff

Positive trends were observed between increasing delivery of nicotine per puff and nicotine per CPM per puff with increasing levels of ammonium carbonate in the unfiltered cigarettes. Nicotine per puff increased from about 0.28 mg/puff (control) to 0.31 mg/puff with percent increases ranging from 4 to 10%. The ratio of nicotine per CPM per puff increased from about 0.0092 (control) to 0.0105 with percent increases ranging from 6 to 14%. The corresponding filtered cigarettes showed similar effects.

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Percent Nicotine Transfer

A positive trend was observed between increasing levels of ammonium carbonate and increases in the percent transfer of nicotine from the leaf to the smoke on a per puff basis for the unfiltered cigarettes. The percent nicotine transfer on a per puff basis increased from 1.5% (control) to 1.6% (2.0% AC). An increase in transfer was not observed in the corresponding filtered cigarettes. Variations in filtration may have obscured the small effect that ammonium carbonate had on the percent nicotine transfer per puff.

Comparative Smoke pH - Filtered Cigarettes

As the percent of added ammonium carbonate was increased, the comparative smoke pH increased from 6.70 (control) to 7.38 (2.0% AC). The observed smoke pH increase for ammonium carbonate cigarettes would increase the calculated percent unprotonated nicotine in an aqueous solution from about 5% (control) to 19% (2.0% AC).

AMMONIUM BICARBONATE

The addition of ammonium bicarbonate (ABC) to cigarette tobacco was found to increase the 1) leaf pH, 2) nicotine per cigarette, 3) number of puffs per cigarette, 4) nicotine per puff, 5) nicotine per CPM and 6) smoke pH. A summary of the effects of adding ammonium bicarbonate to cigarette tobacco, based on results from statistical evaluations of the analytical data, is shown below.

Tobacco Chemistry

The addition of ammonium bicarbonate to the tobacco did not affect the percent nicotine, the percent nitrogen or the percent TRS in the tobacco blend. As the percent added ammonium bicarbonate was increased, corresponding increases were seen in the percent TVB and leaf pH of the tobacco.

Mainstream Smoke Delivery

The addition of ammonium bicarbonate to cigarettes without filters did not affect the following mainstream smoke variables: 1) CPM per cigarette, 2) CPM per puff and 3) nicotine per CPM per puff. Results from the filtered and unfiltered cigarette were similar.

The addition of ammonium bicarbonate to unfiltered cigarettes was found to affect the following smoke variables: 1) nicotine per cigarette, 2) number of puffs per cigarette, 3) nicotine per puff and 4) nicotine per CPM.

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Nicotine per Cigarette, Nicotine per Puff and Nicotine per CPM

For unfiltered cigarettes, the values of nicotine per cigarette, nicotine per puff and nicotine per CPM were higher for cigarettes containing ammonium bicarbonate than for the control cigarettes. There was no trend where increases in the smoke variable corresponded to increases in the percent additive. Rather there appeared to be a threshold concentration, less than or equal to 0.5% ammonium bicarbonate, above which the impact of the additive was not related to concentration.

Nicotine per cigarette increased from 2.3 mg/cig (control) to 2.7 mg/cig with percent increases ranging from 8 to 17%. Nicotine per puff increased from 0.28 mg/puff (control) to 0.32 mg/puff with percent increases ranging from 6 to 13%. Nicotine per CPM increased from 0.077 (control) to 0.090 with percent increases ranging from 9 to 17%. Similar increases were seen with filtered cigarettes.

Number of Puffs per Cigarette

The addition of ammonium bicarbonate in unfiltered cigarettes at the 2.0% level increased the number of puffs per cigarette by 8% from 8.3 puff/cigarette to about 9.0 puff/cigarette. The puff count of cigarettes containing lower levels of ammonium bicarbonate were not different from that of the control. Similar results were obtained for filtered cigarettes.

Percent Nicotine Transfer

No trend was observed between increasing levels of ammonium bicarbonate and increases in the percent transfer of nicotine from the leaf to the smoke for either the unfiltered or the filtered cigarettes.

Comparative Smoke pH - Filtered Cigarettes

As the percent of added ammonium bicarbonate was increased, the comparative smoke pH increased from 6.70 (control) to 7.26 (2.0% ABC). The observed smoke pH increase for ammonium bicarbonate cigarettes would increase the percent unprotonated nicotine in an aqueous solution from about 5% (control) to 15% (2.0% ABC).

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DIAMMONIUM PHOSPHATE

The addition of diammonium phosphate (DAP) to cigarette tobacco was found to affect the 1) leaf pH, 2) nicotine per cigarette, 3) CPM per cigarette, 4) number of puffs per cigarette, 4) nicotine per puff, 5) nicotine per CPM, 6) nicotine per CPM per puff and 7) smoke pH. A summary of the effects of adding diammonium phosphate to cigarette tobacco, based on results from statistical evaluations of the analytical data, is shown below.

Tobacco Chemistry

The addition of diammonium phosphate to the tobacco did not affect the percent nicotine, the percent nitrogen or the percent TRS in the tobacco blend. As the percent added diammonium phosphate was increased, corresponding increases were seen in the percent TVB and leaf pH of the tobacco.

Mainstream Smoke Delivery

The addition of diammonium phosphate to cigarettes without filters did not affect the following mainstream smoke variables: 1) CPM per puff and 2) nicotine per CPM. Similar results were obtained from the corresponding filtered cigarette analyses for CPM per puff but not for nicotine per CPM.

The addition of diammonium phosphate to unfiltered cigarettes did affect the following smoke variables: 1) nicotine per cigarette, 2) CPM per cigarette, 3) number of puffs per cigarette, 4) nicotine per puff and 5) nicotine per CPM per puff.

Number of Puffs per Cigarette, Nicotine per Cigarette and CPM per Cigarette

As the percent diammonium phosphate in unfiltered cigarettes increased, corresponding increases were seen in both puffs per cigarette and CPM per cigarette. Puffs per cigarette increased from 8.6 (control) to 9.3 (2.0% DAP) representing an increase of 9%. CPM per cigarette increased from 30.9 mg/cig (control) to 34.0 mg/cig representing an increase of 10%. Similar results were observed for the filtered cigarettes. Nicotine per cigarette for unfiltered cigarettes is different from the control only for cigarettes containing 3% diammonium phosphate. Nicotine per cigarette increased from 2.3 mg/cig (control) to 2.5 mg/cig (3% DAP) representing a 12% increase. For filtered cigarettes, as the percent diammonium phosphate on the tobacco increased corresponding increases were seen in nicotine per cigarette.

The values of nicotine per cigarette, CPM per cigarette and puffs per cigarette were higher for cigarettes containing diammonium phosphate relative to the control cigarettes. The

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increased puff count is probably due to the smolder retardant properties of diammonium phosphate changing the burn characteristics of the cigarettes (5). The increases in observed nicotine per cigarette and CPM per cigarette appear to be mainly due to the increase in the number of puffs per cigarette.

Nicotine per Puff, Nicotine per CPM and Nicotine per CPM per Puff

The results seen for these three smoke variables were possibly influenced by the increased puff count and modified burn chemistry caused by the smolder retardant properties of diammonium phosphate (5). For the unfiltered cigarettes, nicotine per puff was about 4% less than the control for the 1.0% and 2.0% diammonium phosphate cigarettes and about 3% higher than the control for the 3.0% diammonium phosphate cigarettes. For filtered cigarettes, nicotine per puff is slightly higher for the 2.0% and 3.0% diammonium phosphate cigarettes relative to the control. No trends or threshold effects relating the small changes in nicotine per puff to added DAP could be established.

Nicotine per CPM and nicotine per CPM per puff for unfiltered cigarettes were either less than or not different from the control at all diammonium phosphate additive levels. Nicotine per CPM decreased from 0.074 (control) to a minimum of 0.069 representing a -7% change. Nicotine per CPM per puff decreased from 0.0086 (control) to minimum of 0.0077 with decreases ranging from about -6% to -11%. Results for the filtered cigarettes did not correspond to the changes observed for the unfiltered cigarettes.

Percent Nicotine Transfer

No trend was observed between percent nicotine transfer and increasing levels of diammonium phosphate in unfiltered cigarettes. For filtered cigarettes, a positive trend was observed between increasing levels of diammonium phosphate and increases in the percent transfer of nicotine from the leaf to the smoke on a per cigarette basis. The percent nicotine transfer on a per cigarette basis increased from 8.2% (control) to 9.9% (3.0% DAP).

Comparative Smoke pH - Filtered Cigarettes

As the percent of added diammonium phosphate was increased, the comparative smoke pH of the control at 6.74 was not significantly different from those of the diammonium phosphate cigarettes which ranged from 6.68 to 6.79. The calculated percent unprotonated nicotine in an aqueous solution would be about 5% for collected particulates from the control and the diammonium phosphate cigarettes.

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CONCLUSION:

The addition of urea to cigarette tobacco was found to increase smoke pH, but not leaf pH or leaf nicotine. Nicotine per CPM delivery increased with increasing levels of urea in the tobacco of unfiltered cigarettes. The corresponding filtered cigarettes did not show this increase indicating that variations in filtration may have obscured the relatively small effect that urea had on the nicotine per CPM ratio.

The addition of either ammonium carbonate or ammonium bicarbonate to cigarette tobacco was found to increase both smoke pH and leaf pH, but not leaf nicotine. For both additives, increases were observed in nicotine per CPM for both unfiltered and filtered cigarettes. Also, increases in nicotine per puff were observed for both unfiltered and filtered cigarettes containing added ammonium carbonate or ammonium bicarbonate.

The addition of diammonium phosphate was found to increase leaf pH, but not smoke pH or leaf nicotine. Changes in the nicotine delivery of the diammonium phosphate cigarettes appeared to be related to changes in puff count per cigarette that were observed for this additive. For example, a three percent addition of diammonium phosphate resulted in producing about one additional puff per cigarette. The nicotine per CPM per puff in the diammonium phosphate additive cigarettes appeared to decrease compared to the control by 6 to 10%. Diammonium phosphate is known to be a smolder retardant (5), and this property may be a factor in the differences observed between it and the other three additives.

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Table 1. Evaluations of Statistical Analyses of Mainstream Smoke Delivery Data.

In the cases where the additives have a significant effect on the measured variable, the results are in bold typeface in the table. In the cases where the additives did not have a significant effect on the measured variable, the results are in normal typeface. Included in the not significant category are cases where lower concentration levels were found to be significant while higher concentration levels were not found to be significant. This indicates that the additive was not the cause for the differences found.

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Additive	DIFFERENCE FOUND? If YES, mark with "Y" and give % DIFFERENCE RELATIVE TO CONTROL. If NO, mark with "-"													
	nic/cig		CPM/cig		puff/cig		nic/puff		nic/CPM		CPM/puff		nic/CPM/puff	
	F*	NF*	F	NF	F	NF	F	NF	F	NF	F	NF	F	NF
Urea @ 0.5%	-	-	-	-	-	-	Y 5.5	-	-	-	-	-	-	-
Urea @ 1.0%	Y 5.0	Y 7.6	-	-	Y 6.1	-	-	-	-	Y 6.9	Y -6.6	-	-	-
Urea @ 1.5%	-	-	-	-	-	-	-	-	-	Y 6.9	-	-	-	-
Urea @ 2.0%	Y 8.9	Y 11.5	-	-	Y 7.3	-	-	-	-	Y 11.1	-	-	-	-
AC @ 0.5%	-	-	Y -7.6	Y -6.0	-	Y -3.9	Y 7.7	-	Y 11.9	Y 6.1	-	-	Y 15.4	Y 7.8
AC @ 1.0%	Y 14.2	Y 5.7	-	-	-	-	Y 11.2	Y 6.6	Y 9.0	Y 7.2	-	-	-	Y 5.8
AC @ 1.5%	Y 15.9	Y 10.5	-	-	-	-	Y 14.4	Y 10.0	Y 13.2	Y 14.2	-	-	Y 9.6	Y 13.9
AC @ 2.0%	-	-	Y -7.9	Y -5.6	-	Y -3.5	Y 6.2	Y 7.2	Y 12.9	Y 9.6	-	-	Y 14.1	Y 13.5
ABC @ 0.5%	Y 20.8	Y 15.8	-	-	-	-	Y 17.6	Y 13.6	Y 18.5	Y 17.2	-	-	Y 14.2	Y 14.6
ABC @ 1.0%	Y 22.6	Y 11.2	-	-	-	-	Y 13.2	Y 10.2	Y 16.5	Y 14.8	-	-	Y 16.1	Y 15.4
ABC @ 1.5%	Y 14.9	Y 7.5	-	-	-	-	Y 10.6	Y 6.8	Y 14.3	Y 9.2	-	-	Y 9.5	-
ABC @ 2.0%	Y 15.8	Y 17.3	-	-	Y 9.6	Y 7.8	Y 6.4	Y 8.8	Y 18.6	Y 16.6	-	-	-	-
DAP @ 1.0%	Y 6.2	-	Y 4.2	-	Y 6.2	-	-	Y -6.2	Y 3.9	Y -6.2	-	-	-	Y -8.9
DAP @ 2.0%	Y 13.2	-	Y 7.9	Y 7.1	Y 6.8	Y 3.9	Y 6.0	Y -6.1	Y 6.9	Y -7.0	-	-	-	Y -10.6
DAP @ 3.0%	Y 16.5	Y 12.4	Y 13.5	Y 10.3	Y 10.7	Y 8.7	Y 6.7	Y 3.6	Y 3.5	-	-	-	Y -6.5	Y -6.3

* NOTE: F = Filtered Cigarettes and NF = Not Filtered Cigarettes

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Table 2. Averaged Smoke Data - used in Trend Statistical Analyses

SMOKING LAB
FILTERED CIGARETTES

ID #	1189	1190	1191	1192	1193	1194	1195	1196	1197	1198	1199	1200	1201
Additive	Control	0.5% Urea	1.0% Urea	1.5% Urea	2.0% Urea	0.5% AC	1.0% AC	1.5% AC	2.0% AC	0.5% ABC	1.0% ABC	1.5% ABC	2.0% ABC
NICOTINE (MG/CIG)	1 260	1 302	1 323	1 293	1 373	1 303	1 438	1 461	1 303	1 523	1 417	1 438	1 459
PUFF COUNT (PUFF/CIG)	8 280	8 161	8 267	8 359	8 089	8 007	8 552	8 460	8 130	8 565	8 318	8 667	8 072
CPM (MG/CIG)	15 730	15 502	15 440	15 679	15 253	14 532	15 454	15 254	14 487	16 027	15 178	15 728	15 850
NIC/PUFF	0 151	0 159	0 161	0 154	0 164	0 161	0 166	0 173	0 160	0 178	0 171	0 167	0 181
CPM/PUFF	1 892	1 899	1 867	1 876	1 886	1 815	1 805	1 822	1 783	1 871	1 825	1 815	1 786
NIC/CPM	0 08017	0 08344	0 08576	0 08245	0 08992	0 08967	0 09240	0 09281	0 09004	0 09497	0 09339	0 09267	0 09168
NIC/CPM/PUFF	0 009709	0 010302	0 009279	0 009856	0 009409	0 011060	0 010722	0 010438	0 011074	0 011091	0 011258	0 010830	0 009939

ID #	1340	1341	1342	1343
Additive	DAP Control	1.0% DAP	2.0% DAP	3.0% DAP
NICOTINE (MG/CIG)	1 408	1 497	1 588	1 642
PUFF COUNT (PUFF/CIG)	8 419	8 773	8 895	9 017
CPM (MG/CIG)	18 634	19 417	20 105	20 973
NIC/PUFF	0 167	0 171	0 177	0 175
CPM/PUFF	2 213	2 213	2 235	2 238
NIC/CPM	0 07566	0 07707	0 07837	0 07836
NIC/CPM/PUFF	0 008993	0 008788	0 008825	0 008406

SMOKING LAB
UNFILTERED CIGARETTES

ID #	1189	1190	1191	1192	1193	1194	1195	1196	1197	1198	1199	1200	1201
Additive	Control	0.5% Urea	1.0% Urea	1.5% Urea	2.0% Urea	0.5% AC	1.0% AC	1.5% AC	2.0% AC	0.5% ABC	1.0% ABC	1.5% ABC	2.0% ABC
NICOTINE (MG/CIG)	2 335	2 291	2 508	2 377	2 659	2 288	2 468	2 560	2 416	2 703	2 589	2 511	2 739
PUFF COUNT (PUFF/CIG)	9 312	9 201	9 291	9 254	9 921	9 006	9 416	9 218	9 022	9 430	9 283	9 411	9 361
CPM (MG/CIG)	30 410	29 062	31 828	29 503	31 065	29 580	29 994	29 866	28 711	30 419	30 210	29 952	31 145
NIC/PUFF	0 261	0 279	0 283	0 288	0 297	0 285	0 293	0 309	0 301	0 318	0 310	0 298	0 304
CPM/PUFF	3 654	3 544	3 625	3 574	3 483	3 664	3 565	3 592	3 579	3 612	3 614	3 634	3 475
NIC/CPM	0 07681	0 07892	0 08056	0 08057	0 08531	0 07897	0 08230	0 08782	0 08418	0 09000	0 08755	0 08388	0 09003
NIC/CPM/PUFF	0 009246	0 009025	0 009117	0 009761	0 009584	0 009065	0 009784	0 010578	0 010492	0 010811	0 010687	0 009954	0 009927

ID #	1340	1341	1342	1343
Additive	DAP Control	1.0% DAP	2.0% DAP	3.0% DAP
NICOTINE (MG/CIG)	2 276	2 174	2 270	2 661
PUFF COUNT (PUFF/CIG)	8 567	8 527	8 903	9 308
CPM (MG/CIG)	30 882	31 384	33 041	34 037
NIC/PUFF	0 266	0 255	0 255	0 276
CPM/PUFF	3 602	3 678	3 712	3 657
NIC/CPM	0 07386	0 06929	0 06870	0 07826
NIC/CPM/PUFF	0 008635	0 008128	0 007720	0 008087

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Table 3. Leaf Lab Data for Final Blend (used in Trend Statistical Analyses)

ADDITIVE	PERCENT ADDITIVE	ID#	%NITROGEN	%TVB	%NICOTINE	%TRS	pH
CONTROL	0.0%	1189	3.18	0.64	2.29	7.5	5.47
UREA	0.5%	1190	3.33	0.63	2.33	7.5	5.40
UREA	1.0%	1191	3.52	0.68	2.38	7.4	5.47
UREA	1.5%	1192	3.64	0.68	2.18	7.3	5.53
UREA	2.0%	1193	3.95	0.71	2.30	7.2	5.48
AMM CARB	0.5%	1194	3.70	0.74	2.17	6.9	5.85
AMM CARB	1.0%	1195	3.34	0.68	2.33	7.0	5.95
AMM CARB	1.5%	1196	3.37	0.69	2.27	7.5	6.72
AMM CARB	2.0%	1197	3.35	0.96	2.21	7.2	6.97
AMM BICAR	0.5%	1198	3.33	0.73	2.43	7.2	5.63
AMM BICAR.	1.0%	1199	3.70	0.78	2.26	7.3	5.99
AMM. BICAR.	1.5%	1200	3.34	0.84	2.53	6.9	6.50
AMM BICAR	2.0%	1201	3.24	0.89	2.32	7.3	6.12
DAP CONTRO	0.4%	1340	2.91	0.56	2.05	8.15	5.56
DAP	1.0%	1341	2.95	0.67	2.02	8.05	5.51
DAP	2.0%	1342	2.97	0.76	2.03	8.95	5.57
DAP	3.0%	1343	3.21	0.90	1.99	8.55	5.73

Table 4. Averaged Smoke pH Data (used in Trend Statistical Analyses)

ADDITIVE	PERCENT ADDITIVE	ID#	pH AVG	Calculated % Unprotonated nicotine
CONTROL	0.0%	1189	6.70	4.6
UREA	0.5%	1190	6.78	5.5
UREA	1.0%	1191	6.94	7.6
UREA	1.5%	1192	7.00	10.5
UREA	2.0%	1193	7.10	13.0
AMM CARB	0.5%	1194	6.88	6.7
AMM CARB	1.0%	1195	7.13	11.1
AMM CARB	1.5%	1196	7.36	14.7
AMM CARB	2.0%	1197	7.38	16.5
AMM BICAR.	0.5%	1198	7.07	8.6
AMM BICAR.	1.0%	1199	7.03	9.6
AMM BICAR.	1.5%	1200	7.16	12.0
AMM BICAR.	2.0%	1201	7.24	14.7
DAP CONTROL	0.4%	1340	6.74	5.0
DAP	1.0%	1341	6.75	5.0
DAP	2.0%	1342	6.86	4.4
DAP	3.0%	1343	6.79	6.6

Table 5. PERCENT TRANSFER OF NICOTINE FROM LEAF TO SMOKE (used in Trend Statistical Analyses)

ADDITIVE	PERCENT ADDITIVE	ID#	FILTERED CIGARETTES: CALCULATED PERCENT TRANSFER of NICOTINE PER CIG.	FILTERED CIGARETTES: CALCULATED PERCENT TRANSFER of NICOTINE PER PUFF	UNFILTERED CIGARETTES: CALCULATED PERCENT TRANSFER of NICOTINE PER CIG.	UNFILTERED CIGARETTES: CALCULATED PERCENT TRANSFER of NICOTINE PER PUFF
CONTROL	0.0%	1189	8.5	0.8	12.1	1.5
UREA	0.5%	1190	8.7	0.8	11.7	1.4
UREA	1.0%	1191	8.8	0.8	13.0	1.5
UREA	1.5%	1192	7.8	0.8	12.8	1.6
UREA	2.0%	1193	7.0	0.8	12.5	1.5
AMM CARB	0.5%	1194	7.8	0.9	12.4	1.5
AMM CARB	1.0%	1195	7.3	0.9	12.8	1.5
AMM CARB	1.5%	1196	7.7	0.9	13.6	1.6
AMM CARB	2.0%	1197	7.1	0.9	13.9	1.6
AMM BICAR	0.5%	1198	7.4	0.8	13.1	1.6
AMM. BICAR.	1.0%	1199	7.4	0.9	13.6	1.6
AMM. BICAR.	1.5%	1200	7.4	0.8	13.8	1.5
AMM. BICAR.	2.0%	1201	7.4	0.9	13.8	1.5
DAP CONTRO	0.4%	1340	8.2	1.0	13.2	1.5
DAP	1.0%	1341	8.9	1.0	13.7	1.5
DAP	2.0%	1342	9.3	1.0	13.2	1.5
DAP	3.0%	1343	9.9	1.1	13.4	1.7

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MEMORANDUM

Internal Memo # 4524

PLAINTIFF'S EXHIBIT 10 Dr. Speaks

July 24, 1996

TO: M. A. Sudholt

FROM: J. M. Johnson

SUBJECT: Statistical Evaluations of the Effects of Ammonium Carbonate, Ammonium Bicarbonate, Urea and Diammonium Phosphate on Smoke pH, Smoke Data and Leaf Chemistry

PROJECT NO.: Q 449 Analytical Support

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FINDINGS:

Using statistical analyses of Smoking Lab data, it was shown that the cigarettes with additives had higher values than the control cigarettes for either filtered or unfiltered cigarettes in: 1) nicotine per cigarette for ammonium bicarbonate and diammonium phosphate, 2) nicotine per puff for ammonium carbonate, ammonium bicarbonate and diammonium phosphate, 3) nicotine per CPM for all additives and 4) nicotine per CPM per puff for ammonium carbonate. Using statistical analyses, it was shown that as percent additive levels were increased, corresponding increases were seen in both comparative smoke pH and in tobacco pH for all additives except diammonium phosphate. Tobacco nicotine was not affected by the additives. As the percent additive levels were increased, corresponding increases were seen in nicotine transfer from leaf to smoke for either filtered or unfiltered cigarettes on a per cigarette basis for urea and diammonium phosphate and on a per puff basis for ammonium carbonate.

INTRODUCTION:

The effects of different concentration levels of the additives urea, ammonium carbonate (AC), ammonium bicarbonate (ABC), and diammonium phosphate (DAP) on smoke pH and smoke data on filtered cigarettes and leaf chemistry were reported in two previous memoranda (1,2). This memorandum reports results of statistical evaluation of the previously reported smoke data, smoke pH and leaf chemistry data. In addition, this memorandum includes smoke

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data from the cigarettes with the filters removed and results from the statistical evaluation of this data.

For each measured smoke variable, group and pairwise statistical analyses were performed on individual smoke data from filtered and unfiltered cigarettes. The objective was to determine if mean differences between the cigarettes at all concentrations for a single additive were greater than would be expected by chance and, if so, which concentration level cigarettes were different from the control.

Statistical trend analyses were performed on the average values of smoke data from filtered and unfiltered cigarettes, smoke pH, leaf chemistry data and calculated values of percent nicotine transfer from leaf to smoke of filtered and unfiltered cigarettes. The objective was to determine if the measured variables increased, decreased or did not correlate as the percent additive level was increased.

EXPERIMENTAL

The cigarettes containing urea, ammonium carbonate (AC) or ammonium bicarbonate (ABC) were made with an Old Gold 85 construction. The additives were applied to the tobacco at 0% (the control), 0.5%, 1.0%, 1.5% and 2.0% levels. The cigarettes containing DAP were made with a Newport 85 construction and the additive was applied at 0.4% (the control), 1.0%, 2.0% and 3.0% levels. Refer to the two previous memoranda (1,2) for further details concerning pertinent blend and application process information.

<u>Group and Pairwise Analyses on Smoking Lab Data - Filtered and Unfiltered Cigarettes</u>

Using group statistical analysis for each Smoking Lab measured variable, it was determined if mean differences among the cigarettes at all concentration levels of a single additive were greater than would be expected by chance. Each group consisted of the values of the measured variable for a single additive at all concentration levels including the control level.

In the group analysis, if a significant difference for the measured variable was found, then that meant that cigarettes at one or more concentration levels were different from cigarettes at other concentration levels or from the control. The pairwise tests would then be performed for the measured variable to determine which concentration levels were significantly different from the control.

In the group analysis, if no significant differences were found, then that meant that none of the cigarettes at any concentration level were significantly different from each other or from the

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control cigarettes. In these cases, the pairwise analyses were not performed.

The group statistical analysis used was One Way Analysis of Variance (ANOVA) and the pairwise statistical analysis used was either Dunn's or Dunnett's Pairwise Multiple Comparison. The statistical analyses were run at a 95% confidence level. Dunn's and Dunnett's tests are advanced forms of the student t-test. Dunnett's test was used when the sample sizes were equal and Dunn's test was used when the sample sizes were not equal.

The Smoking Lab measured variables, which were analyzed using these group and pairwise tests, were: 1) mg nicotine per cigarette, 2) mg CPM per cigarette, 3) puff count per cigarette, 4) mg nicotine per puff, 5) mg CPM per puff, 6) nicotine per CPM and 7) nicotine per CPM per puff. Group and pairwise analyses were performed using the individual measurements. For each measured variable, at each additive concentration level, there were two to five individual measurements on the cigarettes containing urea, ammonium carbonate or ammonium bicarbonate and nine to ten individual measurements on the cigarettes containing diammonium phosphate. Each individual measurement was made on the smoke collected from five cigarettes using standard Smoking Lab methods. The cigarettes were smoked and analyzed with the filters and with the filters removed. The Smoking Lab data used in these analyses are shown in Tables 1 through 4.

Trends

Statistical trends analyses were performed to determine if there was an association between increasing levels of percent additive applied and the different measured variables. A positive correlation meant that as the percent additive increased, the measured variable also increased, while a negative correlation meant that as the percent additive increased, the measured variable decreased. No correlation meant that there was no significant relationship between increasing levels of additive and the measured variable. In short, as the percent additive level was increased, the measured variable should have either increased, decreased or not correlated.

The statistical analysis used to determine the presence of these trends was the Pearson Product Moments Correlation run at a 95% confidence level. Correlations were performed on: 1) Smoking Lab data for cigarettes with filters and with filters removed, 2) Leaf Lab data for final blend tobaccos, 3) smoke pH data for filtered cigarettes and 4) calculated values of nicotine transfer from leaf to smoke using cigarettes with filters and with filters removed.

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Smoking Lab Data Trends - Filtered and Unfiltered Cigarettes

The following Smoking Lab measured variables were tested for correlation to percent additive increases: 1) mg nicotine per cigarette, 2) mg CPM per cigarette, 3) puff count per cigarette, 4) mg nicotine per puff, 5) mg CPM per puff, 6) nicotine per CPM and 7) nicotine per CPM per puff. The data, shown in Table 5, were the average of two to five individual measurements for the cigarettes containing the additives of urea, AC or ABC and the average of nine to ten individual measurements for the cigarettes containing the additive DAP. Each individual measurement was made on the smoke collected from five cigarettes using standard Smoking Lab methods. The cigarettes used were made with the final blend containing the additives and were smoked either with the filters or with the filters removed.

Leaf Lab Data Trends

The following Leaf Lab measured variables were tested for correlation to percent additive increases: 1) percent nitrogen, 2) percent total volatile bases (TVB), 3) percent nicotine, 4) percent total reducing substances (TRS) and 5) tobacco pH. The samples used in the Leaf Lab analyses were the final blend tobaccos containing the additives. The data used in the Leaf Lab trends statistical analyses are shown in Table 6.

Smoke pH Data Trends - Filtered Cigarettes

Filtered cigarettes were used in the smoke pH analyses. The smoke pH data used in the correlations were the average of three individual measurements for the additives of urea, AC and ABC and the average of two individual measurements for the additive DAP. Each individual measurement was made on the smoke collected from five cigarettes using a comparative smoke pH method (1,2). The data used in the smoke pH trends statistical analyses are shown in Table 7.

Nicotine Transfer from Leaf to Smoke Trends - Filtered and Unfiltered Cigarettes

The percent transfer of nicotine from leaf to smoke was calculated using the Leaf Lab data of percent nicotine in leaf and the Smoking Lab data of mg nicotine per cigarette, puff count per cigarette and the grams of tobacco per cigarette. The Smoking Lab data were from the cigarettes with filters and with filters removed. The nicotine transfer was calculated on both a per cigarette and a per puff basis. Table 8 lists the data used to make these calculations, an example calculation and the data used in the nicotine percent transfer statistical analyses.

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RESULTS:

Group and Pairwise Analyses on Smoking Lab Data - Filtered and Unfiltered Cigarettes

The Smoking Lab data for filtered and unfiltered cigarettes which were tested for group and pairwise correlations were: 1) mg nicotine per cigarette, 2) mg CPM per cigarette, 3) puff count per cigarette, 4) mg nicotine per puff, 5) mg CPM per puff, 6) nicotine per CPM and 7) nicotine per CPM per puff.

From the results of the group analyses, displayed below, it was shown that there were statistical differences for the majority of the measured variables. This meant that cigarettes at one or more additive concentration levels were different from cigarettes at other additive concentration levels or from the control. For all four additives, statistical differences were found in: 1) nicotine per cigarette for both filtered and unfiltered cigarettes, 2) puff per cigarette and nicotine per puff for filtered cigarettes and 3) nicotine per CPM and nicotine per CPM per puff for unfiltered cigarettes. In CPM per puff for unfiltered cigarettes, for all four additives, no cigarettes at any concentration level were different from the control.

	Filtered Cigarettes		Unfiltered Cigarettes	
Measured Variable	Statistically Significant	Not Statistically Significant	Statistically Significant	Not Statistically Significant
nic/cig	urea AC ABC DAP	-	urea AC ABC DAP	-
CPM/cig	AC DAP	urea ABC	AC DAP	urea ABC
puff/cig	urea AC ABC DAP	-	AC ABC DAP	urea
nic/puff	urea AC ABC DAP	-	AC ABC DAP	urea
CPM/puff	urea	AC ABC DAP	-	urea AC ABC DAP
nic/CPM	AC ABC DAP	urea	urea AC ABC DAP	-
nic/CPM /puff	AC ABC DAP	urea	urea AC ABC DAP	-

For the samples which were found to be significantly different using the group analyses, the pairwise tests were performed to determine which additive level concentration cigarettes were different from the control cigarettes. The results of these tests are displayed on the following page. In the cases where a statistical difference was found using the pairwise test, the average percent difference relative to the control is given.

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Additive	PAIRWISE TESTS RESULTS: IF SAMPLE IS DIFFERENT FROM CONTROL, it is marked "Y" and % DIFFERENCE RELATIVE TO CONTROL is given. If SAMPLE IS NOT DIFFERENT FROM CONTROL, it is marked "-"													
	nic/cig		CPM/cig		puff/cig		nic/puff		nic/CPM		CPM/puff		nic/CPM/puff	
	F*	NF*	F	NF	F	NF	F	NF	F	NF	F	NF	F	NF
Urea @ 0.5%	-	-	-	-	-	-	Y 5.5	-	-	-	-	-	-	-
Urea @ 1.0%	Y 5.8	Y 7.6	-	-	Y 7.3	-	-	-	-	Y 8.3	Y -6.6	-	-	-
Urea @ 1.5%	-	-	-	-	-	-	-	-	-	Y 6.9	-	-	-	-
Urea @ 2.0%	Y 8.9	Y 13.5	-	-	Y 7.3	-	-	-	-	Y 11.1	-	-	-	-
AC @ 0.5%	-	-	Y -7.6	Y -6.0	-	Y -3.9	Y 7.7	-	Y 18.9	Y 6.1	-	-	Y 15.4	Y 7.8
AC @ 1.0%	Y 14.1	Y 5.7	-	-	-	-	Y 18.1	Y 4.4	Y 9.0	Y 7.2	-	-	-	Y 5.0
AC @ 1.5%	Y 15.9	Y 10.5	-	-	-	-	Y 16.4	Y 10.4	Y 13.2	Y 14.3	-	-	Y 9.6	Y 13.9
AC @ 2.0%	-	-	Y -7.5	Y -5.6	-	Y -3.5	Y 6.2	Y 7.2	Y 12.2	Y 9.6	-	-	Y 14.1	Y 33.5
ABC @ 0.5%	Y 20.8	Y 25.8	-	-	-	-	Y 17.6	Y 13.4	Y 18.5	Y 17.2	-	-	Y 14.2	Y 16.8
ABC @ 1.0%	Y 12.6	Y 11.3	-	-	-	-	Y 18.2	Y 10.2	Y 16.5	Y 16.0	-	-	Y 14.1	Y 15.4
ABC @ 1.5%	Y 14.8	Y 7.5	-	-	-	-	Y 10.6	Y 6.0	Y 16.9	Y 9.2	-	-	Y 9.5	-
ABC @ 2.0%	Y 25.8	Y 27.3	-	-	Y 9.6	Y 7.8	Y 6.0	Y 8.0	Y 16.6	Y 14.6	-	-	-	-
DAP @ 1.0%	Y 6.2	-	Y 6.2	-	Y 6.2	-	-	Y -6.2	Y 1.9	Y -6.2	-	-	-	Y -5.9
DAP @ 2.0%	Y 13.2	-	Y 7.3	Y 7.1	Y 6.8	Y 3.9	Y 6.0	Y -8.1	Y 6.9	Y -7.0	-	-	-	Y -10.6
CAP @ 3.0%	Y 16.5	Y 12.4	Y 12.5	Y 10.3	Y 10.7	Y 8.7	Y 4.7	Y 3.4	Y 3.5	-	-	-	Y -6.5	Y -6.3

* NOTE: F = Filtered Cigarettes and NF = Not Filtered Cigarettes

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In nine cases for filtered cigarettes and in seven cases for unfiltered cigarettes, samples at all concentration levels were significantly different from the control. In one case for filtered cigarettes and in four cases for unfiltered cigarettes, samples at all concentration levels except the lowest were significantly different from the control. These results indicate that above a threshold concentration, the additives have a significant effect on the measured variable. These twenty-one cases are in bold typeface on the preceding page.

In most of the remaining cases, either no significant differences relative to the control were found or lower concentration levels were found to be significantly different while higher concentration levels were not found to be significantly different. The latter indicates that the additive concentration level in these cases was not the cause for the differences found.

The values of the percent difference relative to the control were studied for the twenty-one cases in which, above an additive threshold concentration, the cigarettes containing additives were significantly different from the control cigarettes. In nineteen of the twenty-one cases, the values of percent difference relative to the control were positive values. Positive values meant that the cigarettes with additives had higher values than the control cigarettes for the measured variables. In two cases - nicotine per puff and nicotine per CPM per puff for DAP in unfiltered cigarettes - most of the values of percent difference relative to the control were negative values. Negative values meant that the cigarettes with additives had lower values than the control cigarettes for the measured variables.

In comparing the results obtained for filtered and unfiltered cigarettes, it was found that there was good agreement between the two. This indicated that filtration was not changing the effects of the additives. In seven pairs of cases, for both the filtered and unfiltered cigarettes, above a threshold concentration the additives had a significant effect on the measured variable and positive values for percent differences relative to the control. These seven cases were: 1) nicotine per cigarette for ABC, 2) CPK per cigarette for DAP, 3) puff per cigarette for DAP, 4) nicotine per puff for AC and ABC and 5) nicotine per CPM for AC and ABC.

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Trends

Smoking Lab Data Trends - Filtered and Unfiltered Cigarettes

The Smoking Lab measured variables which were tested for correlation to percent additive increases were: 1) mg nicotine per cigarette, 2) mg CPM per cigarette, 3) puff count per cigarette, 4) mg nicotine per puff, 5) mg CPM per puff, 6) nicotine per CPM and 7) nicotine per CPM per puff.

The correlation results from the Pearson Product Moment Correlation are displayed below. The majority of the measured variables showed no correlation to increasing concentration of additives.

Trends were found for three measured variables - nicotine per puff for urea in unfiltered cigarettes and CPM per puff for ABC in both filtered and unfiltered cigarettes - in which previously no significant differences were found using the group analyses of the individual values. This indicates that these trends were not statistically significant after all, but instead were due to randomly distributed data.

Trends were found for eight measured variables - 1) nicotine per cigarettes for DAP for filtered cigarettes, 2) CPM per cigerette and puff per cigaretts for DAP for both filtered and unfiltered cigarettes, 3) nicotine per puff for AC for unfiltered cigarettes, 4) nicotine per CPM for urea for unfiltered cigarettes and 5) nicotine per CPM per puff for AC for unfiltered cigarettes - in which previously significant differences were found using the group analyses. This is a further indication that these trends were statistically significant.

	Filtered Cigarettes			Unfiltered Cigarettes		
Measured Variable	Pos. Cor.	Neg. Cor.	No Cor.	Pos. Cor.	Neg. Cor.	No Cor.
nic/cig	DAP	-	urea AC ABC	-	-	urea AC ABC DAP
CPM/cig	DAP	-	urea AC ABC	DAP	-	urea AC ABC
puff/cig	DAP	-	urea AC ABC	DAP	-	urea AC ABC
nic/puff	-	-	urea AC ABC DAP	urea* AC	-	ABC DAP
CPM/puff	-	ABC*	urea AC DAP	-	ABC*	urea AC DAP
nic/CPM	-	-	urea AC ABC DAP	urea	-	AC ABC DAP
nic/CPM/ puff	-	-	urea AC ABC DAP	AC	-	urea ABC DAP

* NOTE: Not statistically significant based on results from the group analyses.

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Leaf Lab Data Trends

The Leaf Lab data which were tested for correlation to percent additive increases were: 1) percent nitrogen, 2) percent total volatile bases (TVB), 3) percent nicotine, 4) percent total reducing substances (TRS) and 5) leaf pH. The correlation results from the Pearson Product Moment Correlation are listed below. Half of the analyses showed a positive correlation. This meant that increases in the measured variable corresponded to increases in the percent additive. For all additives, percent nicotine did not correlate to increases in the percent additive.

Measured Variable	Positive Correlation	Negative Correlation	No Correlation
% Nitrogen	urea AC	-	ABC DAP
% TVB	urea AC ABC DAP	-	-
% Nicotine	-	-	urea AC ABC DAP
% TRS	urea	-	AC ABC DAP
Leaf pH	AC ABC DAP	-	urea

Smoke pH Data Trends

Using the correlation results from the Pearson Product Moment Correlation, it was shown that, for the additives of urea, ammonium carbonate and ammonium bicarbonate, as the level of percent additive was increased, corresponding increases were seen in smoke pH. No such correlations were seen for the additive DAP. These correlations can be seen graphically in Figure 1.

Nicotine Transfer Data Trends

Using the correlation results from the Pearson Product Moment Correlation displayed below, it was shown that for most of the additives, there was no correlation between nicotine transfer and increasing levels of percent additive. For four analyses, increases in nicotine transfer corresponded to increases in percent additive. These positive correlations were: on a per cigarette basis for urea and DAP in filtered cigarettes and for urea in unfiltered cigarettes and on a per puff basis for AC in unfiltered cigarettes.

	Filtered Cigarettes			Unfiltered Cigarettes		
Nicotine Transfer	Pos. Cor.	Neg. Cor.	No Cor.	Pos. Cor.	Neg. Cor.	No Cor.
per cigarette	urea DAP	-	AC ABC	urea	-	AC ABC DAP
per puff			urea AC ABC DAP	AC	-	urea ABC DAP

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CONCLUSION:

Smoking Lab Data - Filtered and Unfiltered Cigarettes

From statistical trend analyses of Smoking Lab data on filtered and unfiltered cigarettes containing three or four different concentrations of the additives urea, ammonium carbonate, ammonium bicarbonate or diammonium phosphate, it was found that as the percent additive was increased, corresponding increases were seen in the following measured variables:

for filtered cigarettes:
- nicotine per cigarette for diammonium phosphate;
- CPM per cigarette for diammonium phosphate and
- puff per cigarette for diammonium phosphate;

for unfiltered cigarettes:
- CPM per cigarette for diammonium phosphate,
- puff per cigarette for diammonium phosphate,
- nicotine per puff for ammonium carbonate,
- nicotine per CPM for urea and
- nicotine per CPM per puff for ammonium carbonate.

For some measured variables, there was no trend where increases in the measured variable corresponded to increases in the percent additive, but there was a threshold effect. A threshold effect meant that above an additive threshold concentration, the measured variables were higher for cigarettes with additives than for the control cigarettes. This indicates that the measured variable is affected by the additive, but that, for the concentration range tested, the effect does not correspond to the amount of additive present. This threshold effect is illustrated in Figure 2.

For the following Smoking Lab measured variables, a trend was not found but a threshold effect was found:

for filtered cigarettes:
- nicotine per cigarette for ammonium bicarbonate,
- nicotine per puff for ammonium carbonate, ammonium bicarbonate and diammonium phosphate and
- nicotine per CPM for ammonium carbonate, ammonium bicarbonate and diammonium phosphate;

for unfiltered cigarettes:
- nicotine per cigarette for ammonium bicarbonate,
- nicotine per puff for ammonium bicarbonate and
- nicotine per CPM for ammonium carbonate and ammonium bicarbonate.

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Leaf Lab Data

From trend analysis of leaf chemistry data, it was found that as percent additive was increased, the following measured variables showed corresponding increases:

percent nitrogen for urea and ammonium carbonate,
percent TVB for all additives,
percent TRS for urea and
leaf pH for ammonium carbonate, ammonium bicarbonate and diammonium phosphate.

For all additives, percent leaf nicotine did not increase as percent additive was increased.

Smoke pH Data - Filtered Cigarettes

From trend analysis of smoke pH for filtered cigarettes, it was found that as the percent additive was increased, smoke pH increased for urea, ammonium carbonate and ammonium bicarbonate, but not for diammonium phosphate.

Nicotine Transfer - Filtered and Unfiltered Cigarettes

From trend analysis of percent transfer of nicotine from leaf to smoke, it was found that as percent additive was increased, the percent nicotine transfer increased for:

Filtered cigarettes:
on a per cigarette basis for urea and diammonium phosphate;

Unfiltered cigarettes:
on a per cigarette basis for urea and
on a per puff basis for ammonium carbonate.

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Table 1. Smoke Data for Individual Analyses - used in Group and Pairwise Statistical Analyses

Additive = Urea, Ammonium Carbonate (AC), or Ammonium Bicarbonate (ABC)
FILTERED CIGARETTES

ID #	1189	1190	1191	1192	1193	1194	1195	1196	1197	1198	1199	1200	1201
Additive	Control	0.5% Urea	1.0% Urea	1.5% Urea	2.0% Urea	0.5% AC	1.0% AC	1.5% AC	2.0% AC	0.5% ABC	1.0% ABC	1.5% ABC	2.0% ABC
NICOTINE (MG/CIG)	1.182	1.274	1.378	1.300	1.270	1.303	1.385	1.451	1.319	1.420	1.406	1.472	1.418
	1.298	1.304	1.311	1.284	1.174	1.331	1.391	1.415	1.355	1.456	1.433	1.481	1.464
	1.257	1.303	1.302	1.256	1.267	1.319	1.353	1.448	1.287	1.870	1.412	1.492	1.442
	1.207	1.306	1.301	1.272	1.410	1.228	1.354	1.525	1.382	1.542		1.357	1.500
	1.270	1.321		1.341		1.281	1.407	1.472	1.324	1.503			1.473
PUFF COUNT (PUFF/CIG)	8.200	8.209	8.260	8.200	8.000	7.942	8.557	8.208	8.020	8.400	8.318	8.598	8.200
	8.318	8.253	8.776	8.552	8.016	7.942	8.757	8.200	8.238	8.417	8.318	8.000	8.110
	8.318	8.000	8.429	8.223	8.926	8.000	8.571	8.400	8.000	8.805		8.918	8.985
	8.285	8.000	8.882	8.200	9.000	8.000	8.400	8.000	8.085	8.528		8.882	8.983
		8.375		8.670		8.143	8.778	8.894	8.319	8.585		8.480	
CPM (MG/CIG)	15.337	15.795	16.644	16.005	16.040	14.638	16.617	16.294	14.773	15.496	15.106	15.77	15.869
	16.308	14.458	16.436	15.998	16.136	14.463	16.686	15.737	15.437	15.228	14.928	15.838	14.876
	15.700	15.218	14.785	15.201	16.023	14.930	15.675	15.999	14.843	16.016	15.439	16.328	15.061
	14.852	15.856	15.001	15.341	16.842	13.871	17.110	16.557	14.768	15.979		14.973	16.634
	16.230	16.153		15.801		14.863	15.971	16.684	14.614	16.728			17.081
MG/PUFF	0.144	0.155	0.148	0.159	0.152	0.172	0.174	0.177	0.184	0.169	0.172	0.171	0.154
	0.151	0.158	0.148	0.151	0.154	0.160	0.170	0.173	0.152	0.171	0.170	0.164	0.156
	0.150	0.163	0.154	0.153	0.155	0.164	0.163	0.171	0.161	0.182		0.172	0.167
	0.153	0.164	0.150	0.155	0.157	0.155	0.173	0.177	0.165	0.161		0.161	0.164
		0.158		0.156		0.157	0.161	0.166	0.159	0.166			
CPM/PUFF	1.870	1.824	1.783	1.852	1.763	1.831	1.942	1.985	1.842	1.838	1.785	1.836	1.759
	1.869	1.756	1.758	1.809	1.872	1.821	1.931	1.918	1.831	1.809	1.856	1.778	1.851
	1.766	1.902	1.754	1.849	1.795	1.864	1.863	1.903	1.855	1.891		1.865	1.854
	1.800	1.902	1.732	1.871	1.868	1.734	2.037	1.925	1.827	1.868		1.785	1.899
		1.929		1.829		1.825	1.830	1.877	1.759	1.948			
NIC/CPM	0.07707	0.08068	0.08329	0.08122	0.06536	0.08375	0.08957	0.08805	0.08929	0.09200	0.08771	0.08194	0.08851
	0.07873	0.09000	0.08496	0.08995	0.08295	0.08134	0.08825	0.08417	0.08340	0.08450	0.09598	0.08225	0.09778
	0.07957	0.08563	0.08308	0.08263	0.08056	0.08774	0.08632	0.08908	0.08871	0.09634	0.08146	0.08199	0.09574
	0.08574	0.08250	0.08673	0.08297	0.08372	0.08932	0.08498	0.08711	0.09020	0.09680		0.08130	0.09016
	0.07822	0.08177		0.08455		0.08670	0.08810	0.08818	0.09060	0.08623			0.08574
NIC/CPM/PUFF	0.009399	0.009878	0.009878	0.009905	0.008485	0.010805	0.010444	0.010849	0.011133	0.010957	0.011541	0.010850	0.009670
	0.009666	0.010905	0.010081	0.009465	0.009624	0.011500	0.010083	0.010908	0.011340	0.011227	0.010995	0.010345	0.010510
	0.010428	0.010704	0.010449	0.010049	0.009698	0.010956	0.010370	0.010722	0.010836	0.010830		0.010550	0.010304
	0.009441	0.010912	0.010012	0.010112	0.009293	0.011165	0.010117	0.010710	0.011156	0.011351		0.010706	0.009589
		0.009784		0.009752		0.010590	0.010006	0.009814	0.010807	0.011003			

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Table 2. Smoke Data for Individual Analytes - used in Group and Pairwise Statistical Analyses

Additive = Diammonium Phosphate (DAP)
FILTERED CIGARETTES

ID # / Additive	1340 Control	1341 1.0% DAP	1342 2.0% DAP	1343 3.0% DAP
NICOTINE (MG/CIG)	1.402	1.444	1.637	1.640
	1.431	1.425	1.628	1.648
	1.524	1.514	1.711	1.639
	1.395	1.557	1.698	1.627
	1.283	1.593	1.532	1.579
	1.418	1.507	1.594	1.547
	1.418	1.467	1.591	1.691
	1.444	1.480	1.639	1.608
	1.392	1.486	1.556	1.723
	1.373	1.470	1.650	1.680
PUFF COUNT (PUFF/CIG)	8.200	8.600	8.943	9.400
	8.408	8.686	9.110	9.400
	8.600	8.776	9.009	9.408
	8.600	8.927	9.110	9.384
	8.000	8.810	8.918	9.175
	8.400	8.600	8.910	9.271
	8.400	8.609	9.018	9.378
	8.600	9.050	8.910	9.286
	8.404	8.719	9.217	9.000
	8.405	8.752	8.800	9.143
CPM/PUFF	2.227	2.216	2.236	2.231
	2.221	2.145	2.211	2.255
	2.337	2.284	2.298	2.161
	2.140	2.222	2.208	2.270
	2.102	2.259	2.178	2.233
	2.240	2.241	2.279	2.085
	2.212	2.218	2.232	2.245
	2.338	2.173	2.308	2.348
	2.176	2.280	2.200	2.312
	2.134	2.115	2.211	
NIC/CPM/PUFF	0.00936	0.00881	0.00914	0.00832
	0.00911	0.00900	0.00887	0.00827
	0.00882	0.00901	0.00867	0.00852
	0.00881	0.00879	0.00865	0.00809
	0.00901	0.00888	0.00884	0.00837
	0.00907	0.00866	0.00861	0.00853
	0.00908	0.00893	0.00877	0.00852
	0.00836	0.00858	0.00883	0.00824
	0.00867	0.00872	0.00850	0.00809
	0.00894	0.00908	0.00905	

ID # / Additive	1340 Control	1341 1.0% DAP	1342 2.0% DAP	1343 3.0% DAP
CPM (MG/CIG)	18.262	19.080	20.017	20.068
	18.677	18.835	20.141	21.194
	20.102	20.045	20.815	20.333
	18.466	19.833	20.116	21.405
	18.813	20.128	19.427	20.491
	18.828	19.720	20.302	19.329
	18.582	19.092	20.127	21.048
	20.093	19.452	20.579	21.786
	18.481	19.703	20.273	22.041
	18.106	18.508	19.454	21.135
NIC/PUFF	0.171	0.168	0.183	0.174
	0.170	0.164	0.179	0.175
	0.177	0.173	0.179	0.173
	0.182	0.174	0.174	0.173
	0.162	0.179	0.172	0.171
	0.169	0.171	0.179	0.167
	0.169	0.170	0.176	0.179
	0.166	0.166	0.184	0.160
	0.164	0.172	0.172	
	0.162	0.166	0.176	0.164
NIC/CPM	0.0768	0.0758	0.0818	0.0782
	0.0766	0.0765	0.0808	0.0778
	0.0758	0.0755	0.0781	0.0801
	0.0758	0.0765	0.0786	0.0780
	0.0769	0.0782	0.0769	0.0768
	0.0753	0.0764	0.0785	0.0800
	0.0763	0.0768	0.0790	0.0769
	0.0719	0.0769	0.0796	0.0766
	0.0750	0.0760	0.0783	0.0782
	0.0756	0.0794	0.0797	0.0795

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Table 3. Smoke Data for Individual Analyses - used in Group and Pairwise Statistical Analyses

Additive = Urea, Ammonium Carbonate (AC), or Ammonium Bicarbonate (ABC)
CIGARETTES WITH FILTERS REMOVED

ID #	1189	1190	1191	1192	1193	1194	1195	1196	1197	1198	1199	1200	1201
Additive	Control	0.5% Urea	1.0% Urea	1.5% Urea	2.0% Urea	0.5% AC	1.0% AC	1.5% AC	2.0% AC	0.5% ABC	1.0% ABC	1.5% ABC	2.0% ABC
NICOTINE (MG/CIG)	2.306	2.307	2.336	2.426	2.366	2.321	2.454	2.517	2.361	2.700	2.641	2.615	2.787
	2.283	2.271	2.351	2.396	2.562	2.226	2.353	2.537	2.388	2.640	2.418	2.446	2.534
	2.390	2.142	2.057	2.418	2.709	2.274	2.328	2.586	2.415	2.678	2.703	2.361	2.731
	2.277	2.334		2.330	2.726	2.265	2.457	2.692	2.366	2.709	2.631	2.489	2.663
	2.419	2.312		2.513	2.366	2.369	2.477		2.362			2.642	2.782
PUFF COUNT (PUFF/CIG)	8.142	8.347	9.009	8.400	8.000	8.000	8.343	8.436	8.110	8.400	8.240	8.310	8.000
	8.485	8.409	8.599	8.209	8.837	8.000	8.383	8.178	8.000	8.781	8.040	8.319	8.010
	8.409	8.047	8.981	8.343	8.918	7.843	8.516	8.200	8.017	8.200	8.220	8.486	8.071
	8.175	8.209	8.585	8.209	8.827	8.000	8.485	8.206	8.008	8.200	8.560	8.552	8.079
	8.351	8.000		8.110			8.352	8.558	7.970	8.000		8.486	8.743
CPM (MG/CIG)	28.284	31.331	32.102	30.256	30.084	28.485	30.823	28.783	28.302	29.702	28.413	28.452	30.387
	30.793	27.401	28.300	30.974	30.693	28.710	29.268	28.872	28.527	30.443	28.422	29.826	28.865
	31.321	28.072	30.055	29.425	31.954	28.065	28.586	31.836	29.431	31.914	32.233	30.012	30.837
	28.313	30.049	30.855	28.539	31.920	28.672	30.268	28.066	28.813	30.542	31.815	30.719	32.397
	31.257	28.478		29.927		29.070	30.921	30.840	28.494	29.493	30.365	30.804	30.417
MG/PUFF	0.2832	0.2979	0.2815	0.2886	0.2873	0.2783	0.2941	0.2983	0.2911	0.3310	0.3205	0.3147	0.3097
	0.2691	0.2701	0.2720	0.2919	0.2069	0.2843	0.2843	0.3163	0.2965	0.3024	0.3009	0.2940	0.2844
	0.2842	0.2682	0.2965	0.2898	0.3037	0.2824	0.2958	0.3128	0.3012	0.3266	0.3077	0.2782	0.3011
	0.2785	0.2943		0.2838	0.3080	0.2980	0.2943	0.3154	0.3182	0.3140		0.2910	0.3175
	0.2897	0.2890		0.2852			0.2958		0.2861			0.3113	0.3159
CPM/PUFF	3.504	3.758	3.563	3.602	3.343	3.569	3.708	3.412	3.490	3.536	3.446	3.424	3.710
	3.629	3.262	3.303	3.676	3.424	3.511	3.491	3.544	3.586	3.478	3.535	3.558	3.747
	3.725	3.402	3.699	3.527	3.548	3.803	3.358	3.883	3.671	3.892	3.921	3.537	3.377
	3.586	3.680	3.944	3.477	3.818	3.631	3.587	3.564	3.596	3.725	3.561	3.502	3.596
	3.795	3.589		3.591			3.702	3.589	3.571	3.428		3.617	3.479
MG/CPM	0.07860	0.07961	0.07800	0.08018	0.08398	0.08154	0.07938	0.08742	0.08342	0.09380	0.09285	0.09191	0.08144
	0.07414	0.08278	0.08237	0.07941	0.08437	0.07755	0.08142	0.08757	0.08371	0.08697	0.08511	0.08171	0.08773
	0.07631	0.07844	0.08038	0.08218	0.08558	0.08097	0.08843	0.08022	0.08200	0.08768	0.08550	0.07807	0.08914
	0.07756	0.07767		0.08164	0.08534	0.07837	0.08250	0.08009	0.08871	0.09162	0.08665	0.08102	0.08899
	0.07714	0.08118		0.07942		0.08149	0.08081		0.08282			0.08508	0.08060
MG/CPM/PUFF	0.009678	0.009171	0.008798	0.009546	0.009351	0.009692	0.009592	0.010360	0.010286	0.011142	0.011280	0.011080	0.009175
	0.008738	0.009945	0.009612	0.009673	0.009441	0.010121	0.009713	0.010710	0.010494	0.009032	0.010580	0.009832	0.009848
	0.009074	0.009490	0.008878	0.009650	0.009595	0.009666	0.010381	0.010746	0.010235	0.010093	0.010154	0.009270	0.009827
	0.009502	0.009462		0.009946	0.009658	0.010182	0.009723	0.010283	0.011078	0.010977		0.009474	0.009802
	0.009336	0.009149		0.009783			0.009801		0.010397			0.010145	0.010388

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Table 4. Smoke Data for Individual Analyses - used in Group and Pairwise Statistical Analyses

Additive = Diammonium Phosphate (DAP)
CIGARETTES WITH FILTERS REMOVED

ID #	1340	1341	1342	1343
Additive	Control	1.0% DAP	2.0% DAP	3.0% DAP
NICOTINE (MG/CIG)	2.158	2.242	2.312	2.556
	2.414	2.377	2.254	2.506
	2.306	2.115	2.332	2.778
	2.325	2.263	2.296	2.511
	2.259	2.020	2.264	2.493
	2.131	2.049	2.247	2.495
	2.303	2.209	2.247	2.570
	2.259	2.229	2.365	2.663
	2.233	2.091	2.292	2.619
	2.379	2.079	2.270	2.533
PUFF COUNT (PUFF/CIG)	8.000	8.636	8.778	9.000
	8.710	8.800	8.985	9.306
	8.789	8.575	8.719	9.510
	8.800	8.600	9.000	9.310
	8.819	8.343	9.118	9.265
	8.200	8.400	8.778	9.200
	8.719	8.775	8.775	9.209
	8.000	8.543	9.351	9.578
	8.815	8.200	8.719	9.408
	8.518	8.200	9.000	9.185
CPM/PUFF	3.418	3.623	3.789	3.840
	3.554	3.676	3.728	3.456
	3.653	3.543	3.601	3.796
	3.695	3.793	3.730	3.556
	3.412	3.556	3.634	3.630
	3.645	3.514	3.714	3.652
	3.589	3.691	3.747	3.559
	3.642	3.787	3.716	3.793
	3.638	3.733	3.816	3.625
	3.779	3.674	3.632	3.637
NIC/CPM/PUFF	0.009670	0.007921	0.007964	0.006210
	0.008969	0.007818	0.007491	0.006229
	0.008160	0.008118	0.008054	0.007902
	0.008508	0.008068	0.007516	0.006147
	0.008323	0.008193	0.007969	0.007906
	0.008695	0.008264	0.007856	0.007877
	0.008441	0.007964	0.007771	0.006349
	0.008368	0.008054	0.007568	0.007713
	0.008271	0.008039	0.007900	0.006162
	0.008078	0.008533	0.007716	0.006258

ID #	1340	1341	1342	1343
Additive	Control	1.0% DAP	2.0% DAP	3.0% DAP
CPM (MG/CIG)	27.326	32.024	33.081	34.593
	30.858	34.553	33.482	32.453
	31.695	30.391	31.658	36.029
	31.770	32.611	33.003	33.107
	30.431	29.683	33.139	33.705
	29.869	29.516	32.580	33.870
	31.787	32.367	32.879	32.774
	31.372	32.355	34.005	36.326
	31.336	30.011	33.776	34.104
	32.181	29.719	32.690	33.402
NIC/PUFF	0.2699	0.2537	0.2634	0.2840
	0.2783	0.2701	0.2509	0.2671
	0.2627	0.2406	0.2650	0.2869
	0.2703	0.2638	0.2528	0.2697
	0.2533	0.2432	0.2459	0.2695
	0.2599	0.2439	0.2560	0.2696
	0.2841	0.2506	0.2555	0.2736
	0.2627	0.2609	0.2573	0.2602
	0.2502	0.2550	0.2629	0.2784
	0.2793	0.2535	0.2522	0.2760
NIC/CPM	0.07901	0.07001	0.08069	0.07395
	0.07630	0.07080	0.06730	0.07728
	0.07161	0.06852	0.07022	0.07572
	0.07317	0.06906	0.06773	0.07584
	0.07423	0.06836	0.06711	0.07397
	0.07130	0.06942	0.07065	0.07247
	0.07360	0.07006	0.06818	0.07606
	0.07212	0.06869	0.06925	0.07366
	0.07128	0.06831	0.06868	0.07679
	0.07390	0.06807	0.06844	0.07583

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Table 5. Averaged Smoke Data - used in Trend Statistical Analyses

SMOKING LAB
FILTERED CIGARETTES

ID #	1189	1190	1191	1192	1193	1194	1196	1198	1197	1196	1199	1200	1201
Additive	Control	0.5% Urea	1.0% Urea	1.5% Urea	2.0% Urea	0.5% AC	1.0% AC	1.5% AC	2.0% AC	0.5% ABC	1.0% ABC	1.5% ABC	2.0% ABC
NICOTINE (MG/CIG)	1.283	1.302	1.273	1.283	1.373	1.309	1.438	1.481	1.503	1.525	1.417	1.446	1.450
PUFF COUNT (PUFF/CIG)	8.280	8.167	8.707	8.309	8.609	8.007	8.552	8.460	8.150	8.585	8.318	8.667	8.072
CPM (MG/CIG)	15.738	15.502	15.440	15.670	18.263	14.532	16.434	16.234	14.487	16.027	15.178	15.728	15.950
NIC/PUFF	0.151	0.159	0.151	0.154	0.154	0.169	0.168	0.180	0.180	0.178	0.171	0.167	0.161
CPM/PUFF	1.882	1.898	1.790	1.874	1.930	1.815	1.925	1.922	1.793	1.871	1.825	1.815	1.786
NIC/CPM	0.09017	0.09418	0.08529	0.08245	0.08042	0.09097	0.09736	0.09124	0.09304	0.09497	0.09339	0.09207	0.09169
NIC/CPM/PUFF	0.009769	0.010302	0.009779	0.009658	0.008695	0.011208	0.010123	0.010068	0.011034	0.011091	0.011266	0.010330	0.009939

ID #	1340	1341	1342	1343
Additive	DAP Control	1.0% DAP	2.0% DAP	3.0% DAP
NICOTINE (MG/CIG)	1.409	1.497	1.566	1.642
PUFF COUNT (PUFF/CIG)	8.419	8.773	8.953	8.317
CPM (MG/CIG)	18.634	18.417	20.106	20.873
NIC/PUFF	0.167	0.171	0.177	0.175
CPM/PUFF	2.213	2.213	2.255	2.234
NIC/CPM	0.07568	0.07707	0.07837	0.07830
NIC/CPM/PUFF	0.008993	0.008788	0.008825	0.008476

SMOKING LAB
UNFILTERED CIGARETTES

ID #	1188	1190	1191	1192	1193	1194	1195	1198	1197	1198	1199	1200	1201
Additive	Control	0.5% Urea	1.0% Urea	1.5% Urea	2.0% Urea	0.5% AC	1.0% AC	1.5% AC	2.0% AC	0.5% ABC	1.0% ABC	1.5% ABC	2.0% ABC
NICOTINE (MG/CIG)	2.305	2.291	2.308	2.377	2.650	2.288	2.488	2.589	2.418	2.703	2.589	2.511	2.736
PUFF COUNT (PUFF/CIG)	8.312	8.201	8.781	8.254	8.971	7.988	8.418	8.318	8.092	8.430	8.293	8.431	8.961
CPM (MG/CIG)	30.410	29.067	31.928	29.303	31.065	26.556	29.894	29.656	28.711	30.419	30.210	29.947	31.145
NIC/PUFF	0.281	0.279	0.263	0.288	0.297	0.295	0.293	0.309	0.301	0.318	0.310	0.296	0.306
CPM/PUFF	3.658	3.544	3.635	3.574	3.465	3.584	3.586	3.582	3.579	3.612	3.614	3.554	3.475
NIC/CPM	0.07581	0.07892	0.08058	0.08057	0.08531	0.07997	0.08239	0.08787	0.08419	0.08900	0.08725	0.08396	0.08800
NIC/CPM/PUFF	0.009246	0.009625	0.009117	0.009781	0.009564	0.009983	0.009784	0.010578	0.010492	0.010611	0.010667	0.009934	0.009827

ID #	1340	1341	1342	1343
Additive	DAP Control	1.0% DAP	2.0% DAP	3.0% DAP
NICOTINE (MG/CIG)	2.278	2.174	2.270	2.581
PUFF COUNT (PUFF/CIG)	8.567	8.527	8.803	8.308
CPM (MG/CIG)	30.867	31.384	33.041	34.097
NIC/PUFF	0.266	0.255	0.258	0.275
CPM/PUFF	3.602	3.679	3.712	3.657
NIC/CPM	0.07396	0.06928	0.06870	0.07526
NIC/CPM/PUFF	0.008635	0.008129	0.007770	0.008087

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Table 6. Leaf Lab Data for Final Blend - used in Trend Statistical Analyses

ADDITIVE	PERCENT ADDITIVE	ID#	%NITROGEN	%TVB	%NICOTINE	VOLUME	%ASH	%TRS	pH	%LOD
CONTROL	0.0%	1189	3.16	0.64	2.29	227	14.9	7.5	5.47	14.05
UREA	0.5%	1190	3.33	0.63	2.33	219	14.7	7.5	5.49	14.17
UREA	1.0%	1191	3.52	0.65	2.29	218	14.7	7.4	5.47	14.17
UREA	1.5%	1192	3.64	0.68	2.48	220	14.9	7.3	5.53	14.35
UREA	2.0%	1193	3.85	0.71	2.39	221	14.6	7.2	5.40	15.00
AMM.CARB	0.5%	1194	3.20	0.74	2.17	212	15.0	6.9	5.65	14.03
AMM.CARB	1.0%	1195	3.34	0.86	2.33	215	14.9	7.5	6.05	14.54
AMM.CARB	1.5%	1196	3.37	0.89	2.27	211	15.0	7.5	6.22	15.09
AMM.CARB	2.0%	1197	3.35	0.96	2.21	221	15.0	7.2	6.37	14.20
AMM. BICAR.	0.5%	1198	3.33	0.73	2.43	205	14.8	7.2	5.63	14.08
AMM. BICAR.	1.0%	1199	3.20	0.79	2.26	207	15.0	7.3	5.90	14.11
AMM. BICAR.	1.5%	1200	3.34	0.84	2.32	213	15.3	6.9	6.10	14.02
AMM. BICAR.	2.0%	1201	3.24	0.89	2.32	217	14.9	7.3	6.12	14.24
DAP CONTROL	0.4%	1340	2.81	0.56	2.05	195	14.3	8.15	5.30	-
DAP	1.0%	1341	2.95	0.62	2.02	188	14.2	8.85	5.51	-
DAP	2.0%	1342	2.97	0.76	2.03	198	14.2	8.95	5.57	-
DAP	3.0%	1343	3.21	0.98	1.99	186	14.4	8.55	5.73	-

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Table 7. Averaged Smoke pH Data - used in Trend Statistical Analyses

ADDITIVE	PERCENT ADDITIVE	ID#	pH AVG
CONTROL	0.0%	1189	6.70
UREA	0.5%	1190	6.78
UREA	1.0%	1191	6.94
UREA	1.5%	1192	7.08
UREA	2.0%	1193	7.19
AMM.CARB	0.5%	1194	6.88
AMM.CARB	1.0%	1195	7.12
AMM.CARB	1.5%	1196	7.26
AMM.CARB	2.0%	1197	7.38
AMM. BICAR.	0.5%	1198	7.01
AMM. BICAR.	1.0%	1199	7.05
AMM. BICAR.	1.5%	1200	7.16
AMM. BICAR.	2.0%	1201	7.25
DAP CONTROL	0.4%	1340	6.74
DAP	1.0%	1341	6.76
DAP	2.0%	1342	6.69
DAP	3.0%	1343	6.79

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Table 8. PERCENT TRANSFER OF NICOTINE FROM LEAF TO SMOKE

ADDITIVE	PERCENT ADDITIVE	ID#	% NIC. In LEAF	CIGARETTE TOBACCO WT (G/CIG)	FILTERED CIGS. NICOTINE In SMOKE (MG/CIG)	FILTERED CIGS. PUFF COUNT per cig.	FILTERED CIGARETTES: CALCULATED PERCENT TRANSFER of NICOTINE PER CIG.	FILTERED CIGARETTES: CALCULATED PERCENT TRANSFER of NICOTINE PER PUFF	UNFILTERED CIGS. NICOTINE in SMOKE (MG/CIG)	UNFILTERED CIGS. PUFF COUNT per cig.	UNFILTERED CIGARETTES: CALCULATED PERCENT TRANSFER of NICOTINE PER CIG.	UNFILTERED CIGARETTES: CALCULATED PERCENT TRANSFER of NICOTINE PER PUFF
CONTROL	0.0%	1189	2.29	0.841	1.26	8.3	6.5	0.8	2.33	8.3	12.1	1.5
UREA	0.5%	1190	2.33	0.837	1.30	8.2	6.7	0.8	2.29	8.2	11.7	1.4
UREA	1.0%	1191	2.29	0.848	1.32	8.0	6.8	0.9	2.51	8.0	13.0	1.5
UREA	1.5%	1192	2.18	0.848	1.29	8.4	7.0	0.8	2.36	8.3	12.9	1.6
UREA	2.0%	1193	2.30	0.854	1.37	8.9	7.0	0.8	2.65	8.9	13.5	1.5
AMM.CARB	0.5%	1194	2.17	0.853	1.30	8.0	7.0	0.9	2.20	8.0	12.4	1.5
AMM.CARB	1.0%	1195	2.33	0.844	1.44	8.8	7.3	0.9	2.47	8.4	12.6	1.5
AMM.CARB	1.5%	1196	2.27	0.838	1.46	8.5	7.7	0.9	2.58	8.3	13.8	1.6
AMM.CARB	2.0%	1197	2.21	0.833	1.30	8.1	7.1	0.9	2.42	8.0	13.1	1.6
AMM. BICAR.	0.5%	1198	2.43	0.851	1.62	8.6	7.4	0.9	2.70	8.4	13.1	1.6
AMM. BICAR.	1.0%	1199	2.20	0.848	1.42	8.3	7.4	0.9	2.60	8.3	13.8	1.6
AMM. BICAR.	1.5%	1200	2.32	0.848	1.45	8.7	7.4	0.8	2.51	8.4	12.8	1.5
AMM. BICAR.	2.0%	1201	2.32	0.853	1.46	9.1	7.4	0.8	2.74	9.0	13.8	1.5
DAP CONTROL	0.4%	1340	2.05	0.840	1.41	8.4	8.2	1.0	2.28	8.6	13.2	1.5
DAP	1.0%	1341	2.02	0.844	1.50	8.8	8.8	1.0	2.17	8.5	12.7	1.5
DAP	2.0%	1342	2.03	0.846	1.60	9.0	9.3	1.0	2.27	8.9	13.2	1.5
DAP	3.0%	1343	1.99	0.836	1.64	9.3	9.9	1.1	2.56	9.3	15.4	1.7

FORMULAS AND EXAMPLE CALCULATION USING UREA @ 0.5%, UNFILTERED CIGARETTES

Formula for % Nicotine transfer on per cig. basis:

(Nicotine in Smoke / Tobacco wt.) / Nic. In Leaf * 100%

Example:

(2.29 mg nic/cig / 0.837g tob/cig) / 0.0233g nic/g tob * 1g / 1000mg * 100% = 11.7%

Formula for % Nicotine transfer on per puff basis:

((Nicotine in Smoke / Tobacco wt.) / Nic. In Leaf) / PUFF COUNT * 100%

Example:

((2.29 mg nic/cig / 0.837g tob/cig) / 0.0233g nic/g tob) / 8.2 puffs/cig * 1g / 1000mg * 100% = 1.4%

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Figure 1. Smoke pH vs. % Additive

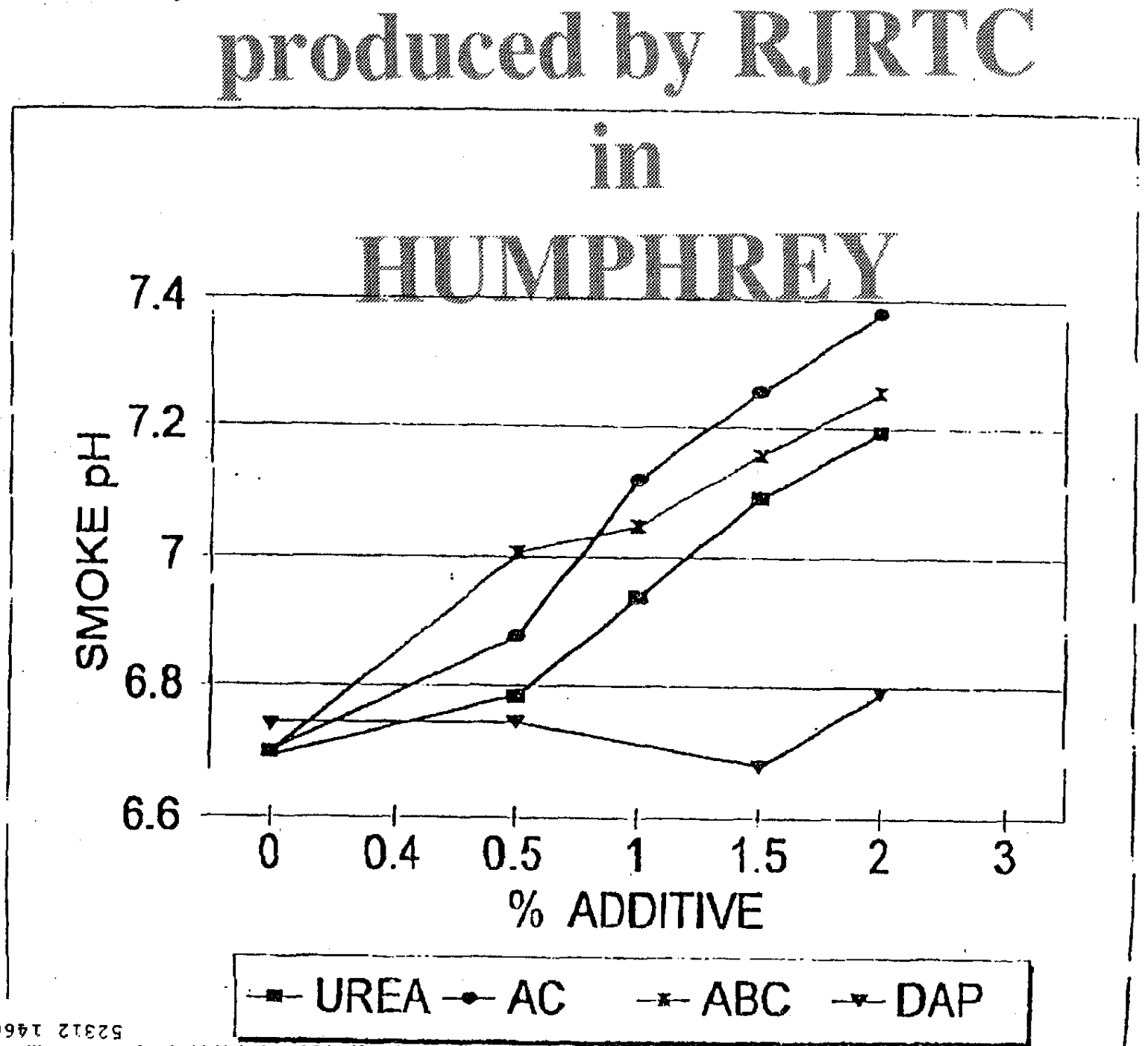

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Figure 2. Threshold Effect vs. Trend Effect

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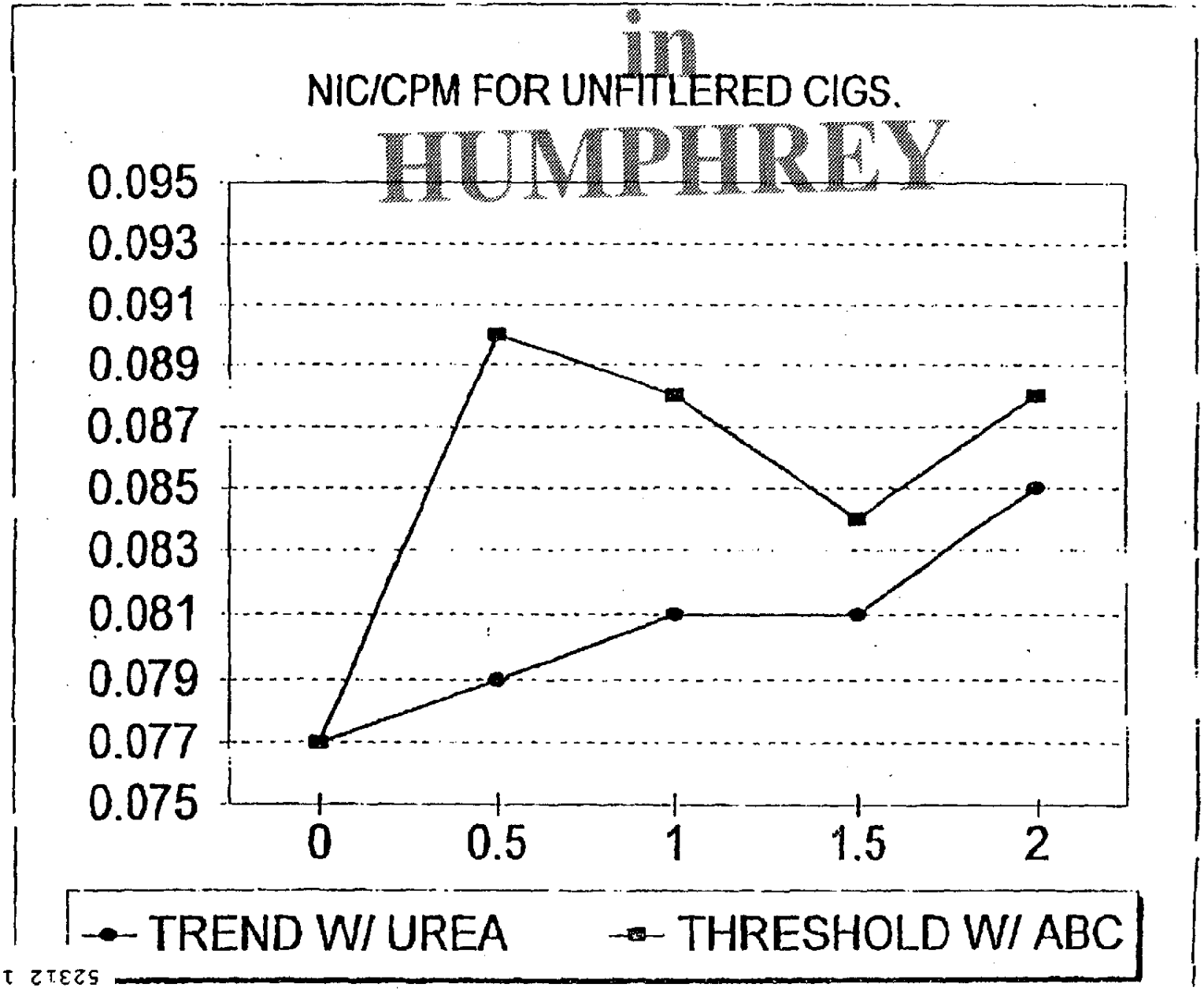

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PLAINTIFF'S EXHIBIT 11 Dr. Spears

DRAFT

2/24/81

T.I. STATEMENT ON "ADDITIVES"

As you know, the then Surgeon General raised various questions with respect to cigarette "additives" in his report released in January. In considering this matter there are a few basic points to be considered.

First, the cigarette manufacturers that are members of the Tobacco Institute are not aware of any substantial scientific evidence suggesting that the flavorings in American cigarettes involve any hazard to health. In this connection, it is my understanding that each manufacturer carefully ~~reviews~~ evaluates information regarding each new flavoring or other additive that it contemplates adding to any of its cigarettes.

Second, since the Surgeon General first expressed his interest in cigarette additives last year, a number of the manufacturers have cooperated by submitting to him lists of cigarette flavorings or other additives, ~~and~~ In addition, their representatives met with him to determine the feasibility of providing additional information as to flavorings in current use. As pointed out to the Surgeon General, and as he appeared to recognize, the precise mixes of flavorings used in individual brands have considerable

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competitive significance and are closely guarded trade secrets. Indeed, insuring the confidentiality of these trade secrets is an important and continuing concern of the cigarette manufacturers.

It bears reemphasizing that there is no substantial scientific evidence that the cigarette flavorings currently in use in the United States present any hazard to health. According to our member companies, there are several reasons for this. ~~Most~~ Many of the flavorings in today's American cigarette have been in use since the 1940's and before. The finest tobaccos have always been the essence of the American cigarette. Flavorings merely fine tune the taste and the introduction of new flavorings represents a continuing refinement. ~~We believe that the total number~~ of new flavorings, industry-wide, since the ~~1940's~~ is probably in the neighborhood of fifteen to twenty, used primarily in connection with low-tar and ultra low-tar ~~cigarettes.~~

~~Of equal importance,~~ It is our understanding that every cigarette manufacturer evaluates information regarding ~~reviews~~ carefully any new flavoring proposed to be added to any of its cigarettes. We are informed that the fundamentals of this evaluation ~~review~~ followed by each of the companies are similar. An important aspect is the thorough review of the published scientific,

Can we say this? Poll the companies?

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and particularly the toxicological, literature. The ~~review~~ evaluation also includes consideration of various lists of substances that have been reviewed and approved for human use, such as the Food and Drug Administration Generally Recognized As Safe (GRAS) list, the Flavorings and Extracts Manufacturers Association list, and listings of substances approved for use in cigarettes by the British Government's Hunter Committee and the Health Office of the Federal Republic of West Germany. The companies also consider other available knowledge, including the opinions of company scientists with special expertise in tobacco chemistry. ~~[as to the behavior of the substance in the cigarette]~~. ~~[In addition, the review is augmented by the parallel reviews of the companies that manufacture flavorings and extracts and supply these products to the cigarette manufacturers.]~~

Does this imply that they are on these lists?

As we have indicated, there seems to be no ~~real~~ substantive ~~basis~~ scientific justification for the emphasis placed on the additives question in the Surgeon General's report. In this connection, it should be noted that two ~~federal government officials~~ scientists*, who were extensively involved in the government's programs dealing with cigarettes, made the following statement in a letter published in the Journal of the American Medical Association in 1979:

> "We know of no scientific evidence that today's additives increase the toxicity of cigarette smoke."

* Footnote omitted in source: April Lynch letter to editor.

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~~[If there is a real need for any further information to be provided,~~ The Institute and its members stand ready to discuss ~~the~~ this matter further with the Department of Health and Human Services. ~~Our members will give their full support to any arrangements that can be worked out with HHS to meet the Department's needs for any further listing of additives in current use.]~~

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PLAINTIFF'S
EXHIBIT
12
Dr. Spears

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK

THE NATIONAL ASBESTOS WORKERS MEDICAL FUND, et al. Plaintiffs, vs. PHILIP MORRIS INCORPORATED (Philip Morris U.S.A.), et al. Defendants.	Case No. 989 Civ. 1492 (JBW) EXPERT REPORT OF DR. ALEXANDER WHITE SPEARS III

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EXPERT REPORT OF DR. ALEXANDER WHITE SPEARS III

BACKGROUND AND QUALIFICATIONS:

I am the Chairman of the Board of Lorillard Tobacco Company. I have worked for Lorillard Tobacco Company and related entities (collectively "Lorillard") from 1959 to the present. I graduated from Allegheny College in 1953 (B.S.) and received my Ph.D. in chemistry from the State University of New York in Buffalo in 1960.

In addition to my current positions with Lorillard, I have served in the following positions at Lorillard since 1959: Research Associate (1959), Senior Research Chemist, Greensboro Division (1961-65), Director, Basic Research (1965-68), Vice President, Research and Development (1971-75), Senior Vice President, Operations and Research (1975-79), Executive Vice President, Operations and Research (1979-1991), Vice Chairman and Chief Operating Officer (1991-95), and

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Chief Executive Officer (1995-98). I have also served as an instructor of chemistry at Millard Fillmore College from 1958 to 1959 and as an Assistant Professor of Chemistry at Guilford College from 1961 to 1965.

I am currently a member of the American Chemical Society, the American Association for Advancement of Science, the Society for Applied Spectroscopy, and the New York Academy of Science. I have served on the Editorial Board of Tobacco Science Journal from 1966 to 1969; as an advisor to the National Cancer Institute from 1968 to the late 1970s; a Member of the Scientific Commission of CORESTA from 1972 to 1976; a member of the U.S. Technical Study Group, Cigarette Safety Act of 1984 from 1984 to 1987; a member of the U.S. CPSC Technical Advisory Group, Fire Safe Cigarette Act of 1990 from 1990 to 1993; Chairman of the Board of Directors for the Center for Indoor Air Research from 1991 to 1995 (and a member from 1988 to the present); and was a member of the Board of Directors for the Council for Tobacco Research-U.S.A., Inc. from 1990 to the present.

I have also contributed research in the areas of pyrolytic reactions and products, spectroscopy, chromatography, analytical methods, structure of natural products, and tobacco and foods.

SUMMARY OF OPINIONS

I am being listed as a fact and expert witness in this matter. This report sets forth the expert testimony that I may offer at trial. I am expected to give testimony regarding the research, design, testing and manufacture of Lorillard cigarettes during the relevant time period.

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I may testify about Lorillard's historical awareness of reports regarding the possible relationship between smoking and health and the actions Lorillard took in response to those reports, including Lorillard's cooperation with Dr. Wynder's research attempts to determine the possible relationship between cigarette "tar" and lung cancer. I may also testify about the limitations of the scientific methodology used from time to time in the research relating to smoking and health issues, including mouse skin painting and animal smoke inhalation studies.

I may testify about research Lorillard has sponsored or conducted in-house on smoking and health issues, including research relating to the chemical composition of cigarette smoke. I may also testify concerning Lorillard's efforts to reduce selected components of smoke over time and other historical research efforts, including Lorillard's and others' research in the areas of benzo(a)pyrene, phenols, ciliastasis, and lung clearance mechanisms.

I may testify on the subject of cigarette design and the reduction in "tar" and nicotine levels in cigarettes in the past several decades. I may testify that, in designing cigarettes, Lorillard has responded to scientific and public health concerns and to smokers' demands. I may also testify concerning Lorillard's efforts to modify its products over the years.

I may testify concerning scientifically acceptable standards for the demonstration of causation of chronic diseases in humans. I may also testify that the statistical associations upon which cigarette smoke has been reported to be a risk factor for human diseases do not themselves establish proof of causation in a scientific sense.

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I may testify about my experience as technical adviser to the National Cancer Institute's Tobacco Working Group from 1968 to the late 1970s and offer my expert opinion on the results of research sponsored and reviewed under its auspices. I may testify that Lorillard and other members of the tobacco industry cooperated with and shared research ideas and results with the National Cancer Institute's Tobacco Working Group.

I also may testify about the opinions and basis thereof expressed by the plaintiffs' witnesses relating to cigarette design and manufacture, including any allegations pertaining to "smoker compensation," nicotine "manipulation," "spiking," reconstituted tobacco, pH, ammonia and additives, allegations about Lorillard research and development efforts, and allegations about company research on so-called "safer cigarette."

I may be asked to comment on the opinions expressed by other witnesses in this case and the evidence on which they rely, to the extent such evidence or opinions are within the scope of my expertise.

My expected testimony and opinions may be based upon my education, training, teaching, research, personal experience and expertise, my review of pertinent scientific information and literature, other information reasonably relied on by members of the profession, and my review of information, testimony, and documents concerning this case. I may also rely on documents and materials used by or relevant to the issues raised by plaintiffs' expert witnesses. Included in my Curriculum Vitae, a copy of which is attached hereto as Exhibit A, is a list of my publications upon

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which I may also rely. In addition to the materials and information described herein, I may also base my testimony on the following internal Lorillard documents:

1. Summary of the Effects of Ammonium Carbonate, Ammonium Bicarbonate, Urea and Diammonium Phosphate on Smoke pH, Smoke Data and Leaf Chemistry;

2. Statistical Evaluations of the Effects of Ammonium Carbonate, Ammonium Bicarbonate, Urea and Diammonium Phosphate on Smoke pH, Smoke Data and Leaf Chemistry; and

3. The Effect of Diammonium Phosphate (DAP) on Smoke pH and Nicotine Delivery.

The materials upon which I rely are either publicly available or have been produced into the Minnesota Document Depository. I will not be separately compensated for my services as an expert in this action.

Alexander W. Spears III

Dr. Alexander W. Spears III

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DEPOSITION AND TRIAL TESTIMONY OF ALEXANDER W. SPEARS III NOVEMBER, 1995 - PRESENT		
DATE	**TYPE OF TESTIMONY**	**CASE**
November 16, 1995 November 22, 1995	Trial Testimony	Braun
December 13, 1995	Deposition Testimony	Roth
January 17, 1996	Deposition Testimony	Roth
February 26, 1996 February 28, 1996	Trial Testimony	Roth
March 8, 1996	Trial Testimony	Newman
March 18, 1996	Trial Testimony	Roth
April 17 - 18, 1996	Trial Testimony	Lesnick
August 13 - 14, 1996	Deposition Testimony	Florida - AG
April 15, 1997	Deposition Testimony	Broin & Engle
June 10 - 11, 1997	Deposition Testimony	Sorise
June 12, 1997	Trial Testimony	Sorise
July 24 - 25, 1997	Deposition Testimony	Barnes; Frosina; Hoberman; Hoskins; Small; Florida - AG; Texas - AG; Zito
August 8, 1997 August 18 - 19, 1997	Trial Testimony	Broin
September 23 -25, 1997	Deposition Testimony	Minnesota - AG
March 3, 1998	Trial Testimony	Dunn
June 24, 1998	Deposition Testimony	Washington -AG
September 25, 1998	Deposition Testimony	Minnesota - AG
January 25, 1999	Trial Testimony	Engle
March 17 - 18, 1999	Trial Testimony	Engle
March 5, 1999	Deposition Testimony	Butler
May 19, 1999	Trial Testimony	Butler

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DEPOSITION AND TRIAL TESTIMONY OF ALEXANDER W. SPEARS III NOVEMBER, 1995 - PRESENT		
DATE	**TYPE OF TESTIMONY**	**CASE**
June 16, 1999	Deposition Testimony	*NY Individual Actions:* Anderson; Brand; Evans; Gruder; Guilloteau; Hellen; Iacono; Knutsen; Krochtengel; Leiderman; Litke; Lucca; Maisonet; Perez; Piccione; Reitano; Rinaldi; Schwartz; Siegel; Sprung; Wagner;

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ALEXANDER WHITE SPEARS III
Chairman
Lorillard Tobacco Company
714 Green Valley Road, Greensboro, NC 27408

Residence: [DELETED]

Place of Birth: Grindstone, PA ([DELETED] 1932)

Parents: A. W. Spears, M.D. (dec.) and Eva Elliott Spears (dec.)

Education: B.S. Allegheny College, 1953
Ph.D. State University of NY at Buffalo, 1960

Married: Shirley Spears

Children: Craig Stewart Spears

Service Record: U.S. Army, 1953-55

Experience: Research Associate, State University of NY at Buffalo, 1956-58

Research Fellow, ibid., 1958-59

Instructor, Millard Fillmore College, 1958-59

Research Associate, P. Lorillard Company, 1959-61

Assistant Professor, Guilford College, 1961-65

Senior Research Chemist, Greensboro Division, P. Lorillard Company, 1961-65

Director, Basic Research, P. Lorillard Company, 1965-68

Director, Research and Development, Lorillard, A Division of Loews Theatres, Inc., 1968-71

Vice President, Research and Development, Lorillard, A Division of Loews Theatres, Inc., 1971-75

Senior Vice President, Operations and Research, Lorillard, A Division of Loews Theatres, Inc., 1975-79

Executive Vice President, Operations and Research, Lorillard, A Division of Loews Theatres, Inc., 1979-85, Lorillard, Inc., 1985-89, Lorillard Tobacco Company, 1989-91.

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Vice Chairman and Chief Operating Officer, Lorillard Tobacco Company, 1991-95.

Chairman and Chief Executive Officer, Lorillard Tobacco Company, 1995-99.

Chairman, Lorillard Tobacco Company, 1999 to present.

Lorillard, Inc., Board of Directors, Chairman, 1995-1999.

Lorillard Tobacco Company, Board of Directors, Chairman, 1995 to present.

Professional Memberships and Honors:

American Chemical Society; Society for Applied Spectroscopy; New York Academy of Science; Sigma Xi; American Association for the Advancement of Science; Who's Who in America; Who's Who in Finance and Industry; Who's Who in Science and Engineering. Distinguished Achievement Award in Tobacco Science, Philip Morris, 1970. Honorary Chairman, 1994 Kmart-Greater Greensboro Open. 1994 Junior Achievement Business Leaders Hall of Fame. 1994 YMCA Hall of Fame. YMCA Honorary Life Member, 1996 - . Honorary Appointment to American Judicature Society, 1998. Guest speaker at the Tobacco Merchants Association 84th Annual Dinner Meeting, 1999. 1999 National Brotherhood Award by the National Conference for Community and Justice.

Related Activities:

Editorial Board, Tobacco Science Journal, 1966-69; Advisor, National Cancer Institute, 1968-78; Member, Scientific Commission of CORESTA, 1972-76; Testimony before the Federal Trade Commission regarding development of method for tar and nicotine determination, 1966; Testimony before the U.S. Senate Subcommittee on Health and the Environment of the Committee on Energy and Commerce for Its Hearing on H.F. 1880, 1983; Testimony before the New York Legislature Senate Finance Subcommittee on Fire Safety and Assembly Subcommittee on Volunteer Firemen, 1984. Member, U.S. Technical Study Group, Cigarette Safety Act of 1984 -- 1984-87, and of the U.S. CPSC-Technical Advisory Group, Fire Safe Cigarette Act of 1990 -- 1990-93. Chairman, Board of Directors, Center for Indoor Air Research, 1991-95 (member, 1988 to present); Member, Board of Directors, The Council for Tobacco Research-U.S.A., Inc., 1990-99.

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Testimony before the Subcommittee on Commerce, Consumer Protection and Competitiveness regarding fire-safe cigarettes HR 293 and HR 673, 1990.

Areas of Research: Pyrolytic Reactions and Products; Spectroscopy; Chromatography; Analytical Methods: Structure of Natural Products; Tobacco; Foods.

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Community Activities:

Board of Directors, Greensboro Chamber of Commerce, 1974 & 1975, 1986 & 1987, 1996-99 , Chairman, 1997. Member, Greensboro Community Initiative, 1996- . Chairman, Council on Education, 1974. Nathaniel Greene Award, 1975. Executive Committee, 1987, 1997.

Chairman, Model School Task Force, jointly sponsored by the Board of Education of the Greensboro Public Schools and the Greensboro Chamber of Commerce, 1975.

Board of Directors, United Way of Greensboro, 1980-85; 1997-99. Cabinet Chairman, United Way of Greensboro, 1999. Campaign Chairman, United Way of Greater Greensboro, 1999.

Member, North Carolina Humanities Committee, 1978-81.

General Chairman, Bennett College/United Negro College Fund, 1982 Campaign.

Member, The Governor's Business Committee for Math & Science Education, 1983-84.

Board of Directors, North Carolina Citizens for Business and Industry, 1984-88.

Chairman, Greensboro Public School Fund, 1987.

Greensboro Area Chairman, Triad Girl Scouts Capital Campaign, 1987.

Board of Directors, N.C. A & T University Foundation, 1985-93. Board of Trustees, 1990 - ; Secretary, 1995-97, Vice Chairman, 1997-99; General Chairman, "Focus on Excellence" Fund-Raising Campaign, 1984-86.

Board of Directors, Greensboro National Bank, 1980-91; Vice Chairman,1989; Executive Committee, 1987-91.

General Chairman, Greensboro Historical Museum Capital Campaign, 1988, 1989; Board of Trustees, 1989 - .

Business Advisory Board of University of North Carolina at Greensboro, Joseph M. Bryan School of Business & Economics, 1988-94.

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Board of Directors, Greensboro Development Corporation, 1985 - ; President, 1992-94; Executive Committee, 1987-; Economic Development Committee, 1991-94; Forward Guilford II Executive Committee, 1998 - .

Board of Directors, Greensboro Metro YMCA, 1989-96; Chairman, 1993-95; Executive Committee, 1991-97; Chairman, Hayes-Taylor Capital Campaign 1990. YMCA Hall of Fame, 1994. YMCA Honorary Life Member, 1996 - .

Board of Visitors-Chairman, Greensboro College, 1990-95.

Board of Trustees, Guilford College, 1995 - ; Board of Visitors, 1990, 1991.

Board of Directors, National Conference of Community and Justice (a.k.a. National Conference of Christians and Jews), 1990-92; Chairman, 1991 NCCJ Annual Brotherhood Citation Dinner, Greensboro Chapter. 1999 National Brotherhood Award by the NCCJ.

Piedmont Triad Airport Authority, member, 1993 - ; Treasurer, 1995-97; Vice Chair, 1997-99.

Advisory Council, North Carolina Center for Nonprofits, 1999 -.

Member, Greensboro Sports Council.

Member, Rotary Clubs of Greensboro.

Member, First Presbyterian Church, Greensboro, NC.

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Publications: U.S. Patent Literature

"Metabolic Alteration of 2-Methylthio-4-Amino-5-Hydroxymethylpyrimidine (Methioprim)." Proceedings for the Society of Experimental Biology and Medicine, 102:239 (1959). Slotnik, Irving J., Spears, A. W., and Tieckelmann, H.

"The Synthesis of Some 2,4,5-Trisubstituted Pyrimidines." Journal of Organic Chemistry, 25:2137 (1960). Peters, E., Minnemeyer, H.J., Spears, A.W., and Tieckelmann, H.

"The Synthesis of Phthaloyltauryl Peptides." Journal of Organic Chemistry, 26:1498 (1961). Spears, A.W. and Tieckelmann, H.

"The Determination of Saturated Hydrocarbons in Cigarette Smoke Condensate." 16th Tobacco Chemists' Research Conference, 1962. Spears, A.W., Lassiter, C.W., and Bell, J.H.

"Quantitative Determination of Alkanes in Cigarette Smoke." Journal of Chromatography, 34 (1963). Spears, A.W., Lassiter, C.W., and Bell, J.H.

"Quantitative Determination of Phenol in Cigarette Smoke." Analytical Chemistry, 35:320 (1963). Spears, A.W.

"Selective Filtration of Volatile Phenolic Compounds from Cigarette Smoke." Tobacco Science, 7:76 (1963). Spears, A.W.

"A Combined Approach to the Quantitative Analyses of the Volatile Components of Cigarette Smoke." 18th Tobacco Chemists' Research Conference, October 20-22, 1964, Raleigh, NC. Spears, A.W. and Routh, W.E.

"An In Vitro Technique for Studying the Ciliastatic Properties of Solutions, Gases, and Aerosol." 18th Tobacco Chemists' Research Conference, October 20-22, 1964, Raleigh, NC. Spears, A.W., Tryviates, G.P., and Schultz, F.J.

"Determination of Moisture in Total Particulate Matter." Tobacco Science, 10:75 (1966). Schultz, F.J. and Spears, A.W.

"The Contributions of Tobacco Constituents to Phenol Yield of Cigarettes." Tobacco Science, 10:138 (1966). Bell, J.W., Saunders, A.O., and Spears, A.W.

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"Difference in Ciliotoxicity of Cigarette Smoke. Comparison of Two Exposure Methods. "American Review of Respiratory Disease, 96:1078 (1967). Dalhamn, T., Rylander, R., and Spears, A.W.

"The Isolation and Identification of Oxygenated Aromatic Hydrocarbons from Cigarette Smoke Condensate." 22nd Tobacco Chemists' Research Conference, 1968. Bell, J.H., Ireland, M.S., and Spears, A.W.

"A Convenient Synthesis of the True 6,7-Acechrysene." Journal of Organic Chemistry, 34: 1176 (1969). Lewis, C.I., Chang, J.Y., and Spears, A.W.

"Identification of Alkylated Phenanthrenes in Cigarette Smoke Condensate." 23rd Tobacco Chemists' Research Conference, 1969. Bell, J.H., Ireland, M.S., Schultz, F.J., and Spears, A.W.

"Identification of Aromatic Ketones in Cigarette Smoke Condensate." Analytical Chemistry, 41:310 (1969). Bell, J.H., Ireland, M.S., and Spears, A.W.

"Preliminary Studies of Substituted Phenanthrene Preparation via Photocyclization of Stilbenes and Butadienes." 23rd Tobacco Chemists' Research Conference, 1969. Lewis, C.I., Chang, J.Y., Schultz, F.J., and Spears, A.W.

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